EXHIBIT 4

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 29, 2017
or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission File Number : 001-35803

Mallinckrodt public limited company

(Exact name of registrant as specified in its charter)

Ireland	**98-1088325**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

3 Lotus Park, The Causeway, Staines-Upon-Thames,
Surrey TW18 3AG, United Kingdom
(Address of principal executive offices) (Zip Code)
Telephone: +44 017 8463 6700
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of each exchange on which registered**
Ordinary shares, par value $0.20 per share	New York Stock Exchange

Securities registered pursuant to section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act

Large accelerated filer	☒	Accelerated filer	☐	Non-accelerated filer	☐	Smaller reporting company	☐	Emerging growth company	☐

(Do not check if smaller reporting company)

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant (assuming solely for the purposes of this calculation that all directors and executive officers of the Registrant are "affiliates") as of June 30, 2017, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $4,352.8 million (based upon the closing price of $44.81 per share as reported by the New York Stock Exchange on that date).

The number of shares of the registrant's common stock outstanding as of February 23, 2018 was 86,350,357.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's definitive proxy statement for its annual meeting of shareholders, to be filed with the Securities and Exchange Commission within 120 days after December 29, 2017, are incorporated by reference into Part III of this report.

MALLINCKRODT PLC
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Presentation of Information

Unless the context requires otherwise, references to "Mallinckrodt plc," "Mallinckrodt," "we," "us," "our" and "the Company" refer to Mallinckrodt plc, an Irish public limited company, and its consolidated subsidiaries for periods subsequent to its separation from Covidien plc on June 28, 2013. For periods prior to June 28, 2013, these terms refer to the combined historical business and operations of Covidien plc's Pharmaceuticals business as it was historically managed as part of Covidien plc. Unless the context requires otherwise, references to "Covidien" refer to Mallinckrodt's former parent company, Covidien plc, an Irish public limited company, and its consolidated subsidiaries (which was subsequently acquired by Medtronic plc). References in this Annual Report on Form 10-K to the "Separation" refer to the legal separation and transfer of Covidien's Pharmaceuticals business to Mallinckrodt plc through a dividend distribution to Covidien shareholders on June 28, 2013. References to "dollars" or "$" refer to United States dollars.

Trademarks and Trade Names

Mallinckrodt owns or has rights to use trademarks and trade names that it uses in conjunction with the operation of its business. One of the more important trademarks that it owns or has rights to use that appears in this Annual Report on Form 10-K is "Mallinckrodt," which is a registered trademark or the subject of pending trademark applications in the United States and other jurisdictions. Solely for convenience, the Company only uses the ™ or ® symbols the first time any trademark or trade name is mentioned. Such references are not intended to indicate in any way that the Company will not assert, to the fullest extent permitted under applicable law, its rights to its trademarks and trade names. Each trademark or trade name of any other company appearing in this Annual Report on Form 10-K is, to the Company's knowledge, owned by such other company.

Forward-Looking Statements

The Company has made forward-looking statements in this Annual Report on Form 10-K that are based on management's beliefs and assumptions and on information currently available to management. Forward-looking statements include, but are not limited to, information concerning the Company's possible or assumed future results of operations, business strategies, financing plans, competitive position, potential growth opportunities, potential operating performance improvements, the effects of competition and the effects of future legislation or regulations. Forward-looking statements include all statements that are not historical facts and can be identified by the use of forward-looking terminology such as the words "believe," "expect," "plan," "intend," "project," "anticipate," "estimate," "predict," "potential," "continue," "may," "should" or the negative of these terms or similar expressions.

Forward-looking statements involve risks, uncertainties and assumptions. Actual results may differ materially from those expressed in these forward-looking statements. You should not place undue reliance on any forward-looking statements.

The risk factors included in Item 1A. of this Annual Report on Form 10-K could cause the Company's results to differ materially from those expressed in forward-looking statements. There may be other risks and uncertainties that the Company is unable to predict at this time or that the Company currently does not expect to have a material adverse effect on its business.

These forward-looking statements are made as of the filing date of this Annual Report on Form 10-K. The Company expressly disclaims any obligation to update these forward-looking statements other than as required by law.

PART I

Item 1. Business.

Overview

We are a global business that develops, manufactures, markets and distributes specialty pharmaceutical products and therapies. Areas of focus include autoimmune and rare diseases in specialty areas like neurology, rheumatology, nephrology, pulmonology and ophthalmology; immunotherapy and neonatal respiratory critical care therapies; analgesics and gastrointestinal products.

In the past few years, we have executed on Mallinckrodt's ongoing transformation to become an innovation-driven specialty pharmaceuticals growth company through a series of strategic acquisitions and divestitures, developing strong commercial platforms and an increasingly robust pipeline. In doing so, our emphasis has evolved to focus on a development portfolio of treatments for severe and critically ill infants and adults.

Through December 29, 2017, we operated our business in two reportable segments, which are further described below:

- *Specialty Brands* includes branded medicines; and
- *Specialty Generics* includes specialty generic drugs, active pharmaceutical ingredients ("APIs") and external manufacturing.

We completed the sale of our Nuclear Imaging ("Nuclear") business and our contrast media and delivery systems ("CMDS") business on January 27, 2017 and November 27, 2015, respectively. As a result, prior year balances have been recast to present the financial results of these businesses as discontinued operations.

In January 2018, we announced that we entered into a definitive agreement to sell our RECOTHROM® Thrombin topical (Recombinant) ("Recothrom") and PreveLeak™ Surgical Sealant ("PreveLeak") assets to Baxter International, Inc. In February 2018, we acquired Sucampo Pharmaceuticals, Inc., including AMITIZA® (lubiprostone), a leading global product in the branded gastrointestinal market.

To further execute upon our strategic vision, on February 22, 2018, our Board of Directors provided authorization to dispose of three areas of our business, which are referred to collectively as "the Specialty Generics Disposal Group" and include the following: (1) Our Specialty Generics business comprised of our Specialty Generics segment, with the exception of our external manufacturing operations; (2) certain of our non-promoted brands business, which is currently reflected in our Specialty Brands segment; and (3) our ongoing, post-divestiture supply agreement with the acquirer of the CMDS business, which is currently reflected in our Other non-operating segment. Given our shift in focus to patients with severe and critical conditions, the areas within the Specialty Generics Disposal Group no longer align with our strategic vision, as such, beginning in the first quarter of fiscal 2018, the historical financial results attributable to the Specialty Generics Disposal Group will be reflected in our consolidated financial statements as discontinued operations.

For further information on our products and segments, refer to "Our Businesses and Product Strategies" within this Item 1. Business.

Fiscal Year

We historically reported our results based on a "52-53 week" year ending on the last Friday of September. On May 17, 2016, our Board of Directors approved a change in our fiscal year end to the last Friday in December from the last Friday in September. The change in fiscal year became effective for our 2017 fiscal year, which began on December 31, 2016 and ended on December 29, 2017. As a result of the change in fiscal year end, we filed a Transition Report on Form 10-Q on February 7, 2017 covering the period from October 1, 2016 through December 30, 2016 ("the three months ended December 30, 2016") with the comparable period from September 26, 2015 through December 25, 2015 ("the three months ended December 25, 2015"). Fiscal 2016 covers the period from September 26, 2015 through September 30, 2016.

History and Development

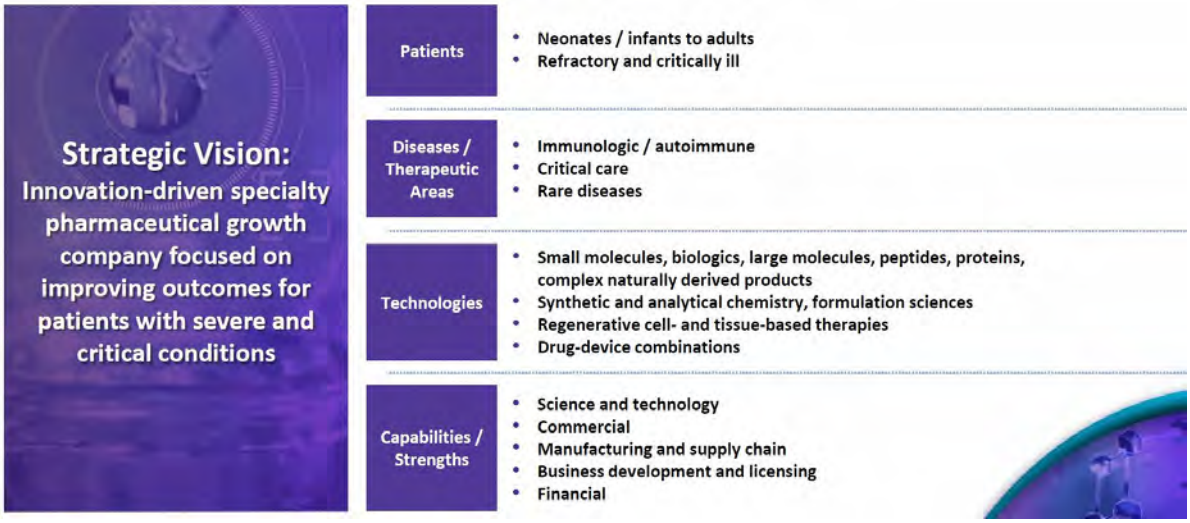
Our development can be traced to the founding of G. Mallinckrodt & Co. in 1867 (predecessor of today's API business). Over the past 150 years, Mallinckrodt has grown to become a global leader in specialty pharmaceuticals on a quest to improve the lives of patients around the world.

Mallinckrodt plc was incorporated in Ireland on January 9, 2013 for the purpose of holding the pharmaceuticals business of Covidien plc ("Covidien"). On June 28, 2013, Covidien shareholders of record received one ordinary share of Mallinckrodt for every eight ordinary shares of Covidien held as of the record date, June 19, 2013, and the pharmaceuticals business of Covidien was transferred to Mallinckrodt plc, thereby completing our legal separation from Covidien ("the Separation").

In May 2015, our Board of Directors approved the migration of our principal executive offices to the United Kingdom ("U.K."), which is located at Three Lotus Park, The Causeway, Staines-upon-Thames, Surrey, TW18 3 AG. In addition, we have other locations in the United States ("U.S."), most notably our corporate shared services office in Hazelwood, Missouri, our Specialty Brands commercial headquarters in Bedminster, New Jersey and our Specialty Generics headquarters and technical development center in Webster Groves, Missouri.

Our Strategic Vision

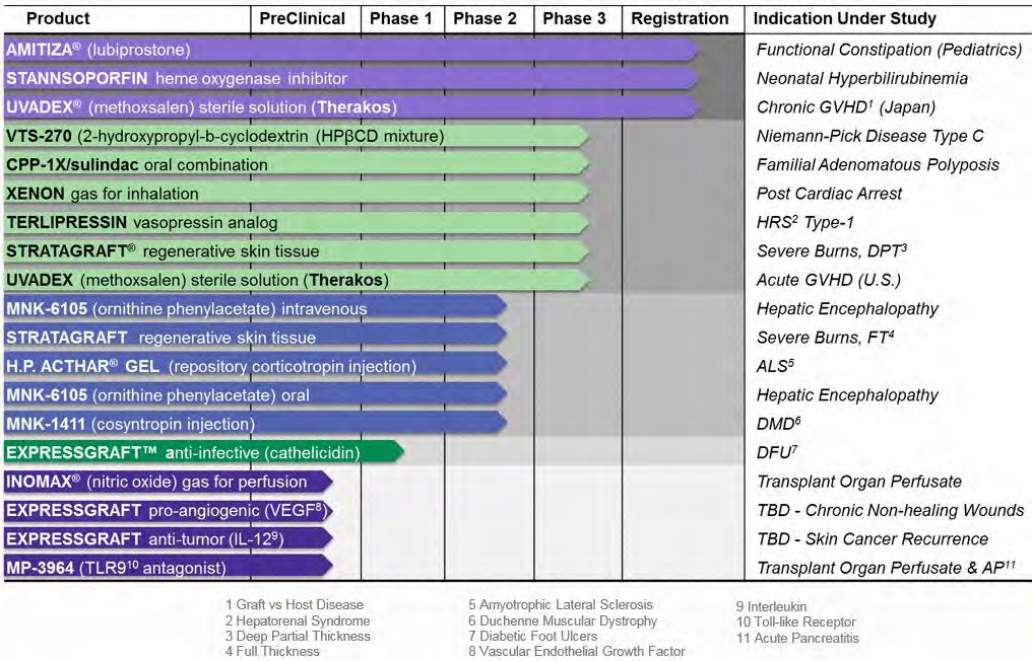
Our Mission: Managing complexity. Improving lives. With this as our guide, our strategic vision is clear:



While we have set forth our strategic vision above, our business involves numerous risks and uncertainties which may prevent us from executing our strategies. For a more complete description of the risks associated with our business, see Item 1A. Risk Factors included within this Annual Report on Form 10-K.

Our Businesses and Products

Through December 29, 2017 and [prior to the announcement of our plan to divest the Specialty Generics Disposal Group] we managed our business in two reportable segments: Specialty Brands and Specialty Generics. Management measures and evaluates our operating segments based on segment net sales and operating income. Information regarding the product portfolios and business strategies of these segments is included in the following discussion. Financial information regarding each of our reportable segments, as well as other geographical information, is included in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations and in Note 21 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.



Specialty Generics

Our Specialty Generics segment markets drugs that include a variety of product formulations containing hydrocodone, oxycodone and several other controlled substances. While our near-term pipeline in this segment is limited, we do have products in development longer-term. Within this segment, we provide bulk API products, including opioids and acetaminophen, to a wide variety of pharmaceutical companies, many of which are direct competitors of our Specialty Generics finished dosage business. In addition, we use our API for internal manufacturing of our finished dosage products. In fiscal 2017, our Specialty Generics segment accounted for 26.5% of net sales from our reportable segments.

We are among the world's largest manufacturers of bulk acetaminophen and the only producer of acetaminophen outside of Asia. We manufacture controlled substances under DEA quota restrictions and in calendar 2017 we estimated that we received approximately 36% of the total DEA quota provided to the U.S. market for the controlled substances we manufacture. We believe that our market position in the API business and allocation of opioid raw materials from the DEA is a competitive advantage for our API business and, in turn, for our Specialty Generics business. The strategy for our API business is based on manufacturing large volumes of high-quality product and customized product offerings, responsive technical services and timely delivery to our customers.

We market our products principally through independent channels, including drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, food store chains with pharmacies, pharmaceutical benefit managers that have mail order pharmacies and hospital buying groups.

The following is a list of significant products and product families in our Specialty Generics product portfolio:

- hydrocodone (API) and hydrocodone-containing tablets;
- oxycodone (API) and oxycodone-containing tablets;
- methylphenidate HCl extended-release tablets USP (CII) ("Methylphenidate ER") under a class BX-rating issued by the FDA in November 2014 and;
- other controlled substances, including acetaminophen (API) products.

Research and Development

We devote significant resources to the research and development ("R&D") of products and proprietary drug technologies. We incurred R&D expenses from continuing operations of $277.3 million, $262.2 million, $203.3 million and $66.2 million in fiscal 2017, 2016 and 2015 and the three months ended December 30, 2016, respectively. We expect to continue to invest in R&D activities, both for existing products and the development of new portfolio assets. We intend to focus our R&D investments principally in the

Backlog

At December 29, 2017, the backlog of firm orders was less than 1% of net sales. We anticipate that substantially all of the backlog as of December 29, 2017 will be shipped during fiscal 2018.

Seasonality

We have historically experienced fluctuations in our business resulting from seasonality. For example, H.P. Acthar Gel has typically experienced lower net sales during the first calendar quarter compared to other calendar quarters, which we believe is partially attributable to effects of annual insurance deductibles and certain medical conditions being exacerbated by warm temperatures. In addition, we have historically experienced lower operating cash flows during the period in which we pay annual employee compensation. In previous years, annual employee compensation was paid during the fourth calendar quarter; however, given the change in our fiscal year end to the last Friday in December from the last Friday in September, we now expect to pay annual employee compensation during the first calendar quarter. DEA quotas for raw materials and final dosage products are allocated in each calendar year to companies and may impact our sales until the DEA grants additional quotas, if any. Impacts from quota limitations are most commonly experienced during the third and fourth calendar quarters, and we have experienced lower net sales in DEA controlled products during the fourth calendar quarter. While we have experienced these fluctuations in the past, they may not be indicative of what we will experience in the future.

Employees

At December 29, 2017, we had approximately 3,900 employees, approximately 3,400 of which are based in the U.S. Certain of these employees are represented by unions or work councils. We believe that we generally have a good relationship with our employees, and with the unions and work councils that represent certain employees.

Executive Officers

Set forth below are the names, ages as of February 1, 2018, and current positions of our executive officers.

Name	Age	Title
Mark Trudeau	56	President, Chief Executive Officer and Director
Matthew Harbaugh	47	Executive Vice President and Chief Financial Officer
Meredith Fischer	65	Chief Public Affairs Officer
Mark Casey	54	General Counsel
Ron Lloyd	57	Executive Vice President and President, Hospital Therapies
Hugh O'Neill	54	Executive Vice President and President, Autoimmune and Rare Diseases
Gary Phillips, MD	51	Executive Vice President and Chief Strategy Officer
Steven Romano, MD	58	Executive Vice President and Chief Scientific Officer
Frank Scholz	49	Executive Vice President of Global Operations and President, Specialty Generics
Karen Sheehy	56	Chief Compliance Officer
Ian Watkins	55	Chief Human Resources Officer

Set forth below is a brief description of the position and business experience of each of our executive officers.

Mark Trudeau is our President and Chief Executive Officer, and also serves on our Board of Directors. In anticipation of the Separation, Mr. Trudeau joined Covidien in February 2012 as a Senior Vice President and President of its Pharmaceuticals business. He joined Covidien from Bayer HealthCare Pharmaceuticals LLC USA, the U.S. healthcare business of Bayer AG, where he served as Chief Executive Officer. He simultaneously served as President of Bayer HealthCare Pharmaceuticals, the U.S. organization of Bayer's global pharmaceuticals business. In addition, he served as Interim President of Bayer's global specialty medicine business unit from January to August 2010. Prior to joining Bayer in 2009, Mr. Trudeau headed the Immunoscience Division at Bristol-Myers Squibb. During his 10-plus years at Bristol-Myers Squibb, he served in multiple senior roles, including President of the Asia/Pacific region, President and General Manager of Canada and General Manager/Managing Director in the United Kingdom. Mr. Trudeau was also with Abbott Laboratories, serving in a variety of executive positions, from 1988 to 1998. Mr. Trudeau has served as a director of TE Connectivity Ltd. since March 2016.

Matthew Harbaugh is our Executive Vice President and Chief Financial Officer. He has executive responsibility for finance, procurement and information technology. Mr. Harbaugh previously served as Vice President, Finance of Covidien's Pharmaceuticals business, a position he held from July 2008 until June 2013, when Mallinckrodt became an independent public company. He also served as Interim President of Covidien's Pharmaceuticals business from November 2010 to January 2012. Mr. Harbaugh joined Covidien's Pharmaceuticals business in August 2007 as its Vice President and Controller, Global Finance for the Global Medical

Imaging business. Mr. Harbaugh was a Lead Finance Executive with Cerberus Capital Management, L.P., a New York-based private equity firm, from April 2007 until August 2007. Prior to that Mr. Harbaugh worked nearly ten years for Monsanto, where he held several positions, including corporate finance director, investor relations, and finance director/chief financial officer for Monsanto's Argentine/Chilean and Canadian operations via two expatriate assignments.

Mark Casey is our General Counsel. Mr. Casey joined Mallinckrodt in February 2018. Before joining Mallinckrodt, Mr. Casey served as Senior Vice President, General Counsel, and Secretary of Idera Pharmaceuticals, Inc., a clinical-stage biopharmaceutical company, from June 2015 to January 2018. Prior to that, Mr. Casey served as Senior Vice President, Chief Administrative Officer, General Counsel, and Secretary at Hologic, Inc., a global medical device and diagnostics company, from March 2012 to December 2014 and as Senior Vice President, General Counsel, and Secretary from October 2007 to March 2012, following Hologic's acquisition of Cytyc Corporation. Prior to the acquisition, Mr. Casey served as Vice President, Deputy General Counsel, and Chief Patent Counsel of Cytyc from 2002 to 2007. Prior to joining Cytyc, Mr. Casey held roles of increasing responsibility at Boston Scientific Corporation and EMC Corporation.

Meredith Fischer is our Chief Public Affairs Officer. In anticipation of the Separation, Ms. Fischer joined Covidien in February 2013 as Vice President, Communications and Public Affairs for its Pharmaceuticals business. Ms. Fischer was employed by Bayer Corporation from 2001 until February 2013, where she served as Vice President of Communications and Public Policy for Bayer HealthCare and Bayer HealthCare Pharmaceuticals, North America. In that role, Ms. Fischer supported Bayer HealthCare's U.S. pharmaceutical and animal health divisions and the company's global medical care and consumer care businesses. She was also Vice President of Marketing and Communications at Pitney Bowes, where she was responsible for product marketing, sales communications and the establishment of professional best practices.

Ron Lloyd is our Executive Vice President and President, Hospital Therapies. Prior to joining Mallinckrodt in January 2016, Mr. Lloyd worked at Baxter Healthcare/Baxalta for 12 years, where he held various commercial leadership positions including: President of the Immunology Division of Baxalta from January to June 2015; Franchise Head, Immunology from January to December 2014; General Manager BioScience U.S. Region from March 2011 to December 2014; General Manager/Vice President - Generative Medicine, Bioscience Division from January 2007 to March 2011; and Vice President - Global Marketing, BioScience Division from April 2003 to December 2006. Mr. Lloyd previously served in a number of commercial and business development capacities at Abbott Laboratories.

Hugh O'Neill is our Executive Vice President and President, Autoimmune and Rare Diseases. From September 2013 to April 2015, he served as Senior Vice President and President, U.S. Specialty Pharmaceuticals. Prior to joining Mallinckrodt in September 2013, Mr. O'Neill worked at Sanofi-Aventis for ten years where he held various commercial leadership positions including Vice President of Commercial Excellence from June 2012 to July 2013; General Manager, President of Sanofi-Aventis Canada from June 2009 to May 2012; and Vice President Market Access and Business Development from 2006 to 2009. Mr. O'Neill joined Sanofi in 2003 as its Vice President, United States Managed Markets. Mr. O'Neill previously served in a variety of positions of increasing responsibility for Sandoz Pharmaceuticals, Forest Laboratories, Novartis Pharmaceuticals and Pfizer.

Gary Phillips, M.D. is our Executive Vice President and Chief Strategy Officer (a role he also held from October 2013 to August 2014). He served as Senior Vice President and President of our Autoimmune and Rare Disease business from August 2014 to January 2015. Before joining Mallinckrodt, Dr. Phillips served as head of Global Health and Healthcare Industries for the World Economic Forum in Geneva, Switzerland from January 2012 to September 2013. Previously, Dr. Phillips served as President of Reckitt Benckiser Pharmaceuticals North America from 2011 to 2012, as Head, Portfolio Strategy, Business Intelligence and Innovation at Merck Serono from 2008 to 2011, and as President of U.S. Pharmaceuticals and Surgical and Bausch & Lomb from 2002 to 2008. Dr. Phillips has also held positions of leadership at Novartis Pharmaceuticals, Wyeth-Ayerst and Gensia Pharmaceuticals. Dr. Phillips serves as a director of Aldeyra Therapeutics, Inc. and Inotek Pharmaceuticals Corp.

Steven Romano, M.D. is our Executive Vice President and Chief Scientific Officer. Dr. Romano joined Mallinckrodt in May 2015 and has executive responsibility for research and development, medical affairs and regulatory affairs functions. Dr. Romano is a board-certified psychiatrist with more than 20 years of experience in the pharmaceutical industry. Previously, Dr. Romano spent 16 years at Pfizer, Inc. where he held a series of senior medical and R&D roles of increasing responsibility, culminating with his role as Senior Vice President, Head, Global Medicines Development, Global Innovative Pharmaceuticals Business. Prior to joining Pfizer, he spent four years at Eli Lilly & Co. After receiving his A.B. in Biology from Washington University in St. Louis and his medical degree from the University of Missouri-Columbia, Dr. Romano completed his residency and fellowship at New York Hospital-Cornell Medical Center, continuing on the faculty of the medical school for six additional years.

Dr. Frank Scholz is our Executive Vice President of Global Operations and President, Specialty Generics. His responsibilities include global manufacturing operations, quality and supply chain, as well as the Specialty Generics segment. He joined Mallinckrodt in March 2014 as Senior Vice President of Global Operations and assumed his current position in September 2016. Prior to joining Mallinckrodt, Dr. Scholz was a partner with McKinsey & Co, a global management consulting firm first in its Hamburg, Germany office and then in its Chicago, Illinois office. Dr. Scholz was a leader in McKinsey's global pharmaceutical and operations practices. He joined McKinsey in 1997. Prior to joining McKinsey, Dr. Scholz was a research assistant at the Institute for Management and Accounting at the University of Hanover, Germany.

Karen Sheehy is our Chief Compliance Officer, a role she assumed in January 2017. Ms. Sheehy joined Mallinckrodt from Sanofi where she worked for more than 15 years, serving most recently as Head of Compliance for North America. Prior to joining Sanofi, Ms. Sheehy worked at Daiichi Pharmaceuticals and was an attorney in private practice at Riker, Danzig, Scherer, Hyland & Perretti LLP where she focused on complex commercial litigation. She began her career as a judicial law clerk for the Honorable Maurice J. Gallipoli, Presiding Judge, Superior Court, Civil Division, Hudson County, New Jersey.

Ian Watkins is our Chief Human Resources Officer. He has executive responsibility for organizational development, effectiveness and sustainability, talent acquisition, total rewards, and human resources systems and service delivery. He is also responsible for supporting the Board of Directors in their governance activities related to executive compensation, talent and succession management. Mr. Watkins joined Covidien's Pharmaceuticals business in September 2012 as the Chief Human Resources Officer. Mr. Watkins served as Vice President, Global Human Resources at Synthes, Inc. from June 2007 to September 2012, which was acquired by Johnson & Johnson. Mr. Watkins served as Senior Vice President, Human Resources from 2003 to 2006 for Andrx Corporation, which is now part of Allergan, Inc. (formerly Actavis, Inc. and Watson Pharmaceuticals, Inc.)

Available Information

Our website address is mallinckrodt.com. We are not including the information contained on our website as part of, or incorporating it by reference into, this filing. We make available to the public on our website, free of charge, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as soon as reasonably practicable after such material is electronically filed with, or furnished to, the U.S. Securities and Exchange Commission ("SEC"). Our reports filed with, or furnished to, the SEC may be read and copied at the SEC's Public Reference Room at 100 F Street, N.E. Washington, DC 20549. Investors may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. These filings are also available on the SEC's website at sec.gov.

We use our website at mallinckrodt.com as a channel of distribution of important company information, such as press releases, investor presentations and other financial information. We also use our website to expedite public access to time-critical information regarding our company in advance of or in lieu of distributing a press release or a filing with the SEC disclosing the same information. Therefore, investors should look to the Investor Relations page of our website for important and time-critical information. Visitors to our website can also register to receive automatic e-mail and other notifications alerting them when new information is made available on the Investor Relations page of our website.

Divestitures

To further execute upon our strategic vision, on February 22, 2018, our Board of Directors provided authorization to dispose of three areas of our business, which are referred to collectively as "the Specialty Generics Disposal Group" and include the following: (1) Our Specialty Generics business comprised of our Specialty Generics segment, with the exception of our external manufacturing operations; (2) certain of our non-promoted brands business, which is currently reflected in our Specialty Brands segment; and (3) our ongoing, post-divestiture supply agreement with the acquirer of the CMDS business, which is currently reflected in our Other non-operating segment. Given our shift in focus to patients with severe and critical conditions, the areas within the Specialty Generics Disposal Group no longer align with our strategic vision, as such, beginning in the first quarter of fiscal 2018, the historical financial results attributable to the Specialty Generics Disposal Group will be reflected in our consolidated financial statements as discontinued operations.

On January 8, 2018, we announced that we entered into a definitive agreement to sell our PreveLeak and Recothrom assets to Baxter International, Inc. ("Baxter") for approximately $185.0 million, with upfront payment of $153.0 million, inclusive of existing inventory, and the remainder in potential future milestones ("the PreveLeak/Recothrom Transaction"). Baxter will assume other expenses, including contingent liabilities associated with PreveLeak upon close of the transaction, which we expect to occur in the first quarter of 2018.

On March 17, 2017, we completed the sale of our Intrathecal Therapy business to Piramal Enterprises Limited's subsidiary in the United Kingdom ("U.K."), Piramal Critical Care ("Piramal"), for approximately $203.0 million, including fixed consideration of $171.0 million and contingent consideration of up to $32.0 million. We recorded a pre-tax gain on the sale of the business of $56.6 million during fiscal 2017, which excluded any potential proceeds from the contingent consideration and reflects a post-sale working capital adjustment. The financial results of the Intrathecal Therapy business are presented within continuing operations as this divestiture did not meet the criteria for discontinued operations classification.

On January 27, 2017, we completed the sale of our Nuclear Imaging business to IBA Molecular ("IBAM") for approximately $690.0 million before tax impacts, including up-front consideration of approximately $574.0 million, up to $77.0 million of contingent consideration and the assumption of certain liabilities. We recorded a pre-tax gain on the sale of the business of $362.8 million during fiscal 2017, which excluded any potential proceeds from the contingent consideration. The financial results for the Nuclear Imaging business, including the recast of prior year balances, are presented within discontinued operations.

On November 27, 2015, we completed the sale of our CMDS business to Guerbet S.A. ("Guerbet") for cash consideration of approximately $270.0 million. The financial results for the CMDS business are presented as a discontinued operation.

Reorganization of Legal Entity Ownership

During the three months ended December 29, 2017, we completed a reorganization of our legal entity ownership ("the Reorganization") to align with our ongoing transformation to become an innovation-driven specialty pharmaceuticals growth company. Many factors were considered in effecting the Reorganization, including streamlining treasury functions, simplifying legal entity reporting processes and capital allocation efficiencies.

Given this Reorganization, the Internal Revenue Code required us to reallocate our tax basis from an investment in shares of a wholly-owned subsidiary to assets within another legal entity with no corresponding change in accounting basis. A deferred tax liability was not recognized on the wholly-owned subsidiary as there is a means for its recovery in a tax-free manner. The reallocation of tax basis resulted in a decrease to the net deferred tax liabilities associated with the assets within the other legal entity. As a result, during fiscal 2017, we recognized an income tax benefit, net of unrecognized tax benefits, of $1,054.8 million primarily as a result of a reduction to our net deferred tax liabilities. The reduction to net deferred tax liabilities was comprised of a $679.3 million reduction to interest-bearing U.S. deferred tax liabilities and the remainder primarily related to reductions to net deferred tax liabilities associated with intangible assets.

Tax Cuts and Jobs Act

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the “TCJA or U.S. Tax Reform”). The TCJA makes broad and complex changes to the U.S. tax code, the effects of which have been incorporated into our fiscal 2017 provision for income taxes, as applicable. The TCJA provisions effective within 2017, include, but are not limited to (1) requiring a one-time transition tax on certain undistributed earnings of our foreign subsidiaries of U.S. entities, (2) bonus depreciation that will allow for full expensing of qualified property, and (3) reducing the U.S. federal corporate statutory tax rate from 35% to 21%. The TCJA also establishes new tax laws that will affect fiscal 2018, including, but not limited to (1) elimination of the corporate alternative minimum tax, (2) creation of the base erosion anti-abuse tax, a new minimum tax, (3) a

EXHIBIT 6

COMMONWEALTH OF KENTUCKY
MADISON COUNTY CIRCUIT COURT
DIVISION NO. II
CIVIL ACTION NO. 18-CI-00381

COMMONWEALTH OF KENTUCKY, *ex rel.*, ANDY BESHEAR, ATTORNEY GENERAL,

Plaintiff.

v.

MALLINCKRODT PLC; MALLINCKRODT LLC, SPECGX LLC,

Defendants.

ORDER DENYING MOTIONS TO DISMISS

1.

This matter is before the Court on a motion by Defendants, Mallinckrodt LLC and SpecGx LLC, to dismiss the Commonwealth's Complaint for failure to state a claim, and on a motion by Defendant Mallinckrodt plc to dismiss the Commonwealth's Complaint for lack of personal jurisdiction and insufficient process. The Court, having reviewed the parties' briefs and conducted a hearing on the matter, hereby rules as follows:

With regard to the Motion to Dismiss for Failure to State A Claim, the Court finds that all counts are sufficiently pled. With regard to each count, the Court finds:

As to Count I, Deceptive Acts and Practices in Violation of Kentucky Consumer Protection Act, and Count II, Restoration of Property due to Violations of Kentucky Consumer Protection Act, the motion is denied. The claims are sufficiently pled under CR 8.01. CR 9.02 does not apply to these claims.

As to Count III, Violations of Kentucky Medicaid Fraud Statute, and Count IV, Violations of Kentucky Assistance Program Fraud Statute, the motion is denied.

As to Count V, Continuing Public Nuisance, the motion is denied. The claim is sufficiently pled pursuant to CR 8.01.

As to Count VI, Fraud, the claim is pled with sufficient particularity under CR 9.02. The motion is denied.

As to Count VII, Unjust Enrichment, the motion is denied. The claims are sufficiently pled under CR 8.01. CR 9.02 does not apply.

As to Count VIII, Negligence, and Count IX, Negligence per se, the motion is denied.

As to Count X, punitive damages, is sufficiently pled and the motion is denied.

With regard to the Motion to Dismiss by Mallinckrodt plc for Lack of Personal Jurisdiction and Insufficient Process, the Court denies the motion without prejudice. Prior to further proceedings against this defendant, the parties are directed to conduct limited discovery regarding the jurisdictional issues raised in the motion and to meet and confer regarding the scope of such discovery. The parties can schedule a hearing with this Court if they are unable to reach an agreement regarding the scope of jurisdictional discovery.

Defendants Mallinckrodt LLC and SpecGx LLC shall have 30 days from the date of entry of the order to answer or otherwise plead.

IT IS SO ORDERED.

ENTERED this 22 day of January __, 2019.

JUDGE, MADISON CIRCUIT COURT

DATE: January 22, 2019

Tendered 18-CI-00381 01/10/2019 David M. Fernandez, Madison Circuit Clerk

HAVE SEEN:
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Counsel for Defendants,
Mallinckrodt LLC and Specgx LLC

Specially appearing for Defendant
Mallinckrodt plc

EXHIBIT 9

Mallinckrodt Advocates for Comprehensive, Multi-Prong Action Plan to Fight Opioid Abuse and Misuse in the United States

--Integrated Policy Initiative Addresses Six Key Contributing Factors--

NEWS PROVIDED BY
Mallinckrodt plc →
Sep 22, 2017, 06:55 ET

ST. LOUIS, Sept. 22, 2017 /PRNewswire/ -- Mallinckrodt plc (NYSE: MNK), an industry leader in the effort to address prescription drug diversion and misuse in the United States, today outlined its "Prescription for America's Opioid Epidemic" – six integrated policy initiatives that the company believes, if implemented, would significantly advance the fight against prescription drug abuse and misuse, and make measurable positive contributions to fight the country's current opioid epidemic.

"As an industry pioneer in addressing the problem of prescription drug diversion and misuse and a strong and constant partner to those focused on addressing the problems of drug abuse, Mallinckrodt has developed a unique perspective on potential policy solutions to address the significant problem facing rural areas, towns and cities in virtually every state in the Union. For years, we have worked with policymakers, law enforcement, patient groups and other stakeholders on the issue of opioid diversion and

abuse, in particular, and will strongly advocate for public policies directed at prevention and treatment," said Mark Trudeau, Chief Executive Officer and President of Mallinckrodt.

Mallinckrodt has developed a policy statement framed around six initiatives in the fight against prescription drug abuse, which is summarized below:

1. **Use Opioids Sparingly:** The preferred standard of care must be a balanced, multimodal approach to pain management. Mallinckrodt will advocate for incentives, policies and treatment guidelines that focus opioid use on cases where adequate pain management cannot be achieved with an alternative therapy, or where alternative therapies are not available or are inappropriate for a particular patient. Mallinckrodt and others offer such alternative medication options today and the company also supports creation of treatment guidelines to advance this approach.
2. **Expand Access to Medication-Assisted Treatment:** All patients with a substance use disorder should have access to appropriate treatment, including counseling, behavioral therapy and all relevant U.S. Food and Drug Administration-approved medications. Mallinckrodt will advocate for federal and state policies that eliminate barriers to treatment access.
3. **Mandate Advanced Education for Healthcare Providers:** Understanding and identifying the risks associated with opioids are critical to better ensuring that healthcare providers can prevent opioid abuse and misuse before it begins. Mallinckrodt has been a strong advocate for continuing medical education for physicians (including dentists and veterinarians), and education of pharmacists and hospital personnel on appropriate prescribing and warning signs of opioid abuse and diversion. The company will continue to advocate for strengthened state and federal policies that mandate such education.
4. **Enhance Regulatory Standards and Data Usage to Prevent Diversion:** Clarifying responsibilities for tracking opioids in the supply chain, generating better data on the nature of opioid abuse – from both legitimate opioid prescriptions and illicit opioid use – and aligning and strengthening prescription drug monitoring programs (PDMPs) across states are critical steps toward halting the diversion and improper use of opioids. Mallinckrodt has been a leading proponent of PDMPs, and will advocate for regulatory clarity and improved data generation and sharing at the federal and state levels.
5. **Urge Safe Drug Storage and Disposal:** Several national statistics reveal that home medicine cabinets are a primary source of diverted prescription opioids, and so it is critically important to form public and

private partnerships to provide ways to safely and responsibly store medications and dispose of unused and unneeded medication. As one such solution, Mallinckrodt has donated approximately 1.5 million drug disposal pouches across the United States and will increase that number incrementally to 2 million by the first quarter of 2018. Some states have also purchased drug disposal pouches for their residents, and Mallinckrodt will advocate for funding to continue these efforts.

6. **Fund Community-Based Education / Intervention:** Education on opioid abuse and community interventions with youth and at-risk populations is critical to achieving healthy and drug-free communities. Mallinckrodt will continue to advocate for federal funding, made available through the Comprehensive Addiction and Recovery Act, and state funding to support community-based education and intervention programs.

Mallinckrodt believes that these six policy initiatives will have a significant impact on reducing opioid abuse and misuse in communities across the United States. The company will continue to actively engage with policymakers, law enforcement, patient groups, and other stakeholders to achieve these policy goals. For more information on Mallinckrodt's work to combat prescription drug abuse and misuse, please visit www.mallinckrodt.com/solutions.

ABOUT MALLINCKRODT

Mallinckrodt is a global business that develops, manufactures, markets and distributes specialty pharmaceutical products and therapies. Areas of focus include autoimmune and rare diseases in specialty areas like neurology, rheumatology, nephrology, pulmonology and ophthalmology; immunotherapy and neonatal respiratory critical care therapies; and analgesics and hemostasis products. The company's core strengths include the acquisition and management of highly regulated raw materials and specialized chemistry, formulation and manufacturing capabilities. The company's Specialty Brands segment includes branded medicines and its Specialty Generics segment includes specialty generic drugs, active pharmaceutical ingredients and external manufacturing. To learn more about Mallinckrodt, visit www.mallinckrodt.com.

Mallinckrodt uses its website as a channel of distribution of important company information, such as press releases, investor presentations and other financial information. It also uses its website to expedite public access to time-critical information regarding the company in advance of or in lieu of distributing a press release or a filing with the U.S. Securities and Exchange Commission (SEC) disclosing the same information. Therefore, investors should look to the Investor Relations page of the website for important and time-critical information. Visitors to the website can also register to receive automatic e-mail and other notifications alerting them when new information is made available on the Investor Relations page of the website.

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SOURCE Mallinckrodt plc

Related Links

http://www.mallinckrodt.com

EXHIBIT 10

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

DIVISION OF
CORPORATION FINANCE

March 7, 2018

Victor Goldfeld
Wachtell, Lipton, Rosen & Katz
vgoldfeld@wlrk.com

Re: Mallinckrodt plc

Dear Mr. Goldfeld:

This letter is in regard to your correspondence dated March 6, 2018 concerning the shareholder proposal (the "Proposal") submitted to Mallinckrodt plc (the "Company") by Mercy Investment Services, Inc. et al. (the "Proponents") for inclusion in the Company's proxy materials for its upcoming annual meeting of security holders. Your letter indicates that the Proponents have withdrawn the Proposal and that the Company therefore withdraws its January 12, 2018 request for a no-action letter from the Division. Because the matter is now moot, we will have no further comment.

Copies of all of the correspondence related to this matter will be made available on our website at http://www.sec.gov/divisions/corpfin/cf-noaction/14a-8.shtml. For your reference, a brief discussion of the Division's informal procedures regarding shareholder proposals is also available at the same website address.

Sincerely,

Kasey L. Robinson
Attorney-Adviser

cc: Donna Meyer
Mercy Investment Services, Inc.
dmeyer@mercyinvestments.org

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E-MAIL: VGOLDFELD@WLRK.COM

March 6, 2018

VIA EMAIL (SHAREHOLDERPROPOSALS@SEC.GOV)

Office of Chief Counsel
Division of Corporation Finance
U.S. Securities and Exchange Commission
100 F Street, N.E.
Washington, D.C. 20549

Re: *Withdrawal of Shareholder Proposal to Mallinckrodt plc by Mercy Investment Services, Inc., Providence Trust and Catholic Health Initiatives*

Ladies and Gentlemen:

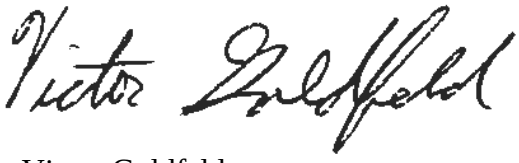
In a letter dated January 12, 2018 and a subsequent supplemental letter dated March 6, 2018 (together, the "No-Action Request"), each of which we submitted on behalf of our client, Mallinckrodt plc, an Irish public limited company ("Mallinckrodt"), we requested that the Staff of the Division of Corporation Finance (the "Staff") of the U.S. Securities and Exchange Commission concur that Mallinckrodt could exclude from its proxy statement and form of proxy for its 2018 Annual General Meeting of Shareholders (collectively, the "2018 Proxy Materials") a shareholder proposal (the "Proposal") and the statement in support thereof

received from Mercy Investment Services, Inc., Providence Trust, and Catholic Health Initiatives (collectively, the "Proponents") for proposed inclusion in the 2018 Proxy Materials.

Enclosed as Exhibit A is a letter dated March 6, 2018 from Ms. Donna Meyer of Mercy Investment Services, Inc. formally withdrawing the Proposal on behalf of the Proponents. In reliance on this letter, we hereby withdraw the No-Action Request and ask that the Staff give no further consideration to this matter. A copy of this letter is being sent simultaneously to the Proponents as notification of Mallinckrodt's withdrawal of the No-Action Request.

If we can be of any further assistance in this matter, please do not hesitate to contact me at (212) 403-1005 or by email to VGoldfeld@wlrk.com.

Very truly yours,



Victor Goldfeld

Enclosures

cc: Mark Casey, Mallinckrodt plc
Stephanie D. Miller, Mallinckrodt plc

Exhibit A

March 6, 2018

Stephanie D. Miller
Vice President, Corporate Secretary and International Legal
Mallinckrodt
675 McDonnell Boulevard
Hazelwood, MO 630242 USA

Dear Ms. Miller:

Thank you for your mail dated March 5, 2018, which informed shareholder proponents that Mallinckrodt Pharmaceuticals is proposing to dispose of its opioid manufacturing business. This intent was further confirmed by the letter today from Andrew Kenny with Wachtell, Lipton, Rosen & Katz.

Based on this information, proponent shareholders, including Mercy Investment Services, Inc., Providence Trust, and Catholic Health Initiatives would like to withdraw the resolution requesting that the board of directors of Mallinckrodt (MNK) prepare a report to shareholders by September 30, 2018, on measures MNK has taken to mitigate business risks related to its opioid business. We agree that the pending divestiture of MNK's opioid manufacturing business substantially undermines the relevance of the requested report to MNK's business and its shareholders. We hope you will withdraw your SEC no-action request.

As shareholders, we will continue to be interested in the long-term success of our Company. We thank staff and independent board members for their concern about the opioid epidemic in the U.S. and their willingness to engage with shareholders about this issue.

Sincerely,

Donna Meyer, PhD

2039 North Geyer Road . St. Louis, Missouri 63131 . 314.909.4609 . 314.909.4694 (fax)

www.mercyinvestmentservices.org

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March 6, 2018

VIA EMAIL (SHAREHOLDERPROPOSALS@SEC.GOV)

Office of Chief Counsel
Division of Corporation Finance
U.S. Securities and Exchange Commission
100 F Street, N.E.
Washington, D.C. 20549

Re: *Shareholder Proposal to Mallinckrodt plc by Mercy Investment Services, Inc., Providence Trust and Catholic Health Initiatives*

Ladies and Gentlemen:

On behalf of our client, Mallinckrodt plc, an Irish public limited company ("Mallinckrodt" or the "Company"), we write to supplement the no-action request letter dated January 12, 2018 that we submitted on behalf of Mallinckrodt (the "Initial Request Letter") regarding the shareholder proposal (the "Proposal") and the statement in support thereof received from Mercy Investment Services, Inc., Providence Trust, and Catholic Health Initiatives (collectively, the "Proponents") for proposed inclusion in Mallinckrodt's proxy statement and

form of proxy for its 2018 Annual General Meeting of Shareholders (collectively, the "2018 Proxy Materials").

We are submitting this letter on behalf of Mallinckrodt to provide information regarding an update to the Company's business plans since the date of the Initial Request Letter and to address certain aspects of the letter dated February 9, 2018 submitted by the Proponents (the "Proponents' Response Letter") to the Staff of the Division of Corporation Finance (the "Staff") of the U.S. Securities and Exchange Commission (the "Commission"), a copy of which is attached hereto as Exhibit A.

Pursuant to Rule 14a-8(j) under the Exchange Act, we have:

- transmitted this letter by email to the Staff at shareholderproposals@sec.gov; and

- concurrently sent copies of this letter, together with its attachments, to the Proponents at the email addresses they have provided.

As counsel to the Company, we continue to request confirmation that the Staff will not recommend enforcement action if the Company excludes the Proposal from the 2018 Proxy Materials for the reasons set forth in the Initial Request Letter and this letter. This letter supplements, and does not replace, the Initial Request Letter.

CHANGE IN THE COMPANY'S BUSINESS PLANS

Since the submission of the Initial Request Letter and the Proponent's Response Letter, as announced by the Company on February 27, 2018, the Company has reclassified its Specialty Generics business segment as discontinued operations, effective as of December 29, 2017. Mallinckrodt plans to dispose of these businesses, which include the Company's opioid manufacturing business, because they do not align with Mallinckrodt's strategic vision of becoming a brands-focused innovation-driven specialty pharmaceutical growth company. The Company continues to believe that the Proposal is excludable from the 2018 Proxy Materials for the reasons set forth in the Initial Request Letter. We will not repeat those reasons here. But the pending divestiture of the Company's opioid manufacturing business substantially undermines the purported relevance, if any, of the proposed report to the Company's business and its shareholders. As noted on page 11 of the Initial Response Letter, "[o]pioid products [already] account for only a small portion—less than 10%—of Mallinckrodt's total revenues." Following the pending divestiture, those revenues will fall to zero.

THE PROPONENTS' RESPONSE LETTER

The Proponent's Response Letter cites a variety of recent articles and reports related to the opioid crisis, including various reports regarding perceived or alleged governance failures by companies other than Mallinckrodt, and in particular Purdue Pharma L.P., a privately held company that manufactures opioid products. These facts (and/or allegations), whatever their validity, are not relevant the Company's governance procedures in general or its historical role in combating the opioid crisis in particular, or to the question of whether the proposal transcends the Company's ordinary business operations or has the necessary nexus to the Company. The mere fact that the Company operates in the same industry is not sufficient to demonstrate that the Proposal is required to be included in the Company's Proxy Materials.

The Proponents also reference the Staff's recent determination that a similar proposal was not excludable by AmerisourceBergen, asserting that "[i]f the nexus is strong enough for a distributor, manufacturers, who are blamed equally, if not more, for opioid misuse, must have a sufficiently strong nexus." This conclusory assertion is made with no support, and it is not supportable. As explained in the Initial Request Letter, Mallinckrodt does not market or promote its opioid products directly to physicians or patients. The Proponents' attempt to paint all manufacturers and distributors with the same broad brush likewise fails to demonstrate that their proposal transcends the Company's ordinary business operations or have the necessary nexus to the Company.

Separately, on page 9, the Proponent's Response Letter refers to the section of the Initial Request Letter explaining that there is not a sufficient nexus between the nature of the Proposal and the Company, because (among other reasons) opioid products constitute only a small portion of Mallinckrodt's revenues (which, as noted above, are now expected to be reduced to zero). The Response Letter asserts that "an argument like this one about nexus should be part of a submission reflecting the board's consideration of the Proposal's subject in the context of the company's business" as contemplated by Staff Legal Bulletin No. 14I, which announced a new Staff policy regarding the application of Rule 14a-8(i)(7). However, the Initial Request Letter states expressly on page 8 that "[t]he Nominating and Governance Committee (the "Governance Committee") of the Board reviewed the Proposal and Supporting Statement in consultation with management, and the discussion herein reflects the review and analyses of the Governance Committee, which was subsequently approved by the full Board, as well as the Company's management."

REQUEST FOR EXCLUSION

The Company respectfully requests that the Staff concur in its view that the Proposal and the Supporting Statement may be excluded from the 2018 Proxy Materials pursuant to (i) Rule 14a-8(i)(7), because the Proposal involves matters that relate to the ordinary business

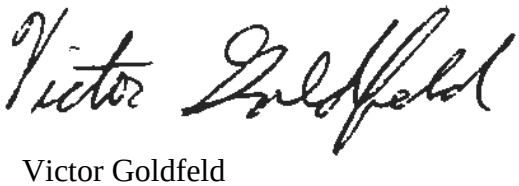
operations of the Company and/or (ii) Rule 14a-8(i)(10), because the Company has already substantially implemented the Proposal.

CONCLUSION

Based on the foregoing and the reasons set forth in the Initial Request Letter, the Company respectfully requests the Staff's concurrence with the Company's view or, alternatively, that the Staff confirm that it will not recommend any enforcement action if the Company excludes the Proposal and the Supporting Statement from the 2018 Proxy Materials.

If we can be of any further assistance in this matter, please do not hesitate to call the undersigned at (212) 403-1005. If the Staff is unable to concur with the Company's conclusions without additional information or discussions, the Company respectfully requests the opportunity to confer with members of the Staff prior to the issuance of any written response to this letter. In accordance with Staff Legal Bulletin No. 14F, Part F (Oct. 18, 2011), please send your response to this letter and in the Initial Request Letter by email to VGoldfeld@wlrk.com.

Very truly yours,



Victor Goldfeld

Enclosures

cc: Mark Casey, Mallinckrodt plc
Stephanie D. Miller, Mallinckrodt plc

Exhibit A

February 9, 2018

Via e-mail at shareholderproposals@sec.gov

Securities and Exchange Commission
Office of the Chief Counsel
Division of Corporation Finance
100 F Street, NE
Washington, DC 20549

Re: Request by Mallinckrodt plc to omit proposal submitted by Mercy Investment Services, Providence Trust and co-filers

Ladies and Gentlemen,

Pursuant to Rule 14a-8 under the Securities Exchange Act of 1934, Mercy Investment Services Inc., Providence Trust and Catholic Health Initiatives (together, the "Proponents") submitted a shareholder proposal (the "Proposal") to Mallinckrodt plc ("Mallinckrodt" or the "Company"). The Proposal asks Mallinckrodt's board to report to shareholders on governance measures ABC has implemented since 2012 to more effectively monitor and manage financial and reputational risks related to the opioid crisis in the U.S.

In a letter to the Division dated January 12, 2018 (the "No-Action Request"), Mallinckrodt stated that it intends to omit the Proposal from its proxy materials to be distributed to shareholders in connection with the Company's 2018 annual meeting of shareholders. Mallinckrodt argues that it is entitled to exclude the Proposal in reliance on Rule 14a-8(i)(7), as relating to Mallinckrodt's ordinary business operations; and Rule 14a-8(i)(10), on the ground that Mallinckrodt has substantially implemented the Proposal. As discussed more fully below, Mallinckrodt has not met its burden of proving its entitlement to rely on either exclusion; accordingly, the Proponents respectfully ask that the Company's request for relief be denied.

The Proposal

The Proposal states:

"RESOLVED, that shareholders of Mallinckrodt plc ("Mallinckrodt") urge the Board of Directors (the "Board") to report to shareholders by September 30, 2018 on the governance measures Mallinckrodt has implemented since 2012 to more effectively monitor and manage financial and reputational risks related to the opioid crisis in the U.S., given Mallinckrodt's sale of opioid medications and active

pharmaceutical ingredients in opioid medications, including whether Mallinckrodt has assigned responsibility for such monitoring to the Board or one or more Board committees, revised senior executive compensation metrics or policies, adopted or changed mechanisms for obtaining input from stakeholders, or altered policies or processes regarding company political activities.

The report should be prepared at reasonable cost and should omit confidential and proprietary information."

Ordinary Business

Mallinckrodt argues that it is entitled to omit the Proposal in reliance on Rule 14a-8(i)(7), which allows exclusion of proposals related to a company's ordinary business operations. Specifically, Mallinckrodt urges that the Proposal's subject is the "manufacture and sale of products" or the Company's compliance program and that the Proposal does not deal with a significant social policy issue with a nexus to Mallinckrodt. Mallinckrodt also claims the Proposal would micromanage the Company.

As discussed below, Mallinckrodt has not met its burden of establishing that the Proposal relates to its ordinary business operations. The Proposal addresses a significant social policy issue with which opioid manufacturers have a strong connection. The Proposal asks for disclosure of governance measures, not a specific policy change or detailed reporting about operations, and thus cannot be said to micromanage Mallinckrodt. Accordingly, the Proponents ask that Mallinckrodt's request for relief be denied.

The Opioid Crisis Is a Significant Social Policy Issue and a Strong Nexus to Opioid Manufacturers Exists

The opioid epidemic is undoubtedly a "sustained" and "consistent topic of widespread public debate," the standard the Staff has applied in determining whether a proposal deals with a significant social policy issue.[1]

According to the Center for Disease Control and Prevention ("CDC"), the number of opioid painkillers dispensed in the U.S. quadrupled from 1999 to 2010, despite no change in reported pain levels.[2] In 2015, opioid overdoses killed more than 33,000 Americans, and that number is expected to be up significantly when official data for 2016 are released.[3] Opioid addiction alone has lowered U.S. average life expectancy by 2.5 months.[4]

The sheer volume of national media coverage, expressions of public sentiment and legislative and regulatory initiatives spawned by the opioid epidemic precludes an exhaustive list. Some key examples are:

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[1] See Exchange Act Release No. 40018 (May 21, 1998); Comcast Corp. (Mar. 4, 2011); Verizon Communications Inc. (Feb. 13, 2012).

[2] https://www.cdc.gov/drugoverdose/epidemic/index.html.

[3] Centers for Disease Control and Prevention data on 2015 deaths (https://www.cdc.gov/drugoverdose/); Lenny Bernstein, "Deaths from Drug Overdoses Soared in the First Nine Months of 2016," The Washington Post, Aug. 8, 2017 (https://www.washingtonpost.com/news/to-your-health/wp/2017/08/08/deaths-from-drug-overdoses-soared-in-the-first-nine-months-of-2016/) ("Given available state data and anecdotal information, many experts are expecting a big increase in deaths in 2016, driven by the worsening crisis in overdoses from opioids, especially fentanyl and heroin").

[4] http://www.chicagotribune.com/news/nationworld/ct-opioids-life-expectancy-20170920-story.html

- President Trump declared the opioid epidemic a public health emergency in October 2017.[5] He has empaneled a Presidential Commission on Combating Addiction and the Opioid Crisis to make recommendations on the federal response.[6]
- During the 2016 Presidential election campaign, addressing the opioid crisis ranked as the most important issue for voters in some areas.[7] Candidates discussed the opioid epidemic on the campaign trail in both the primaries[8] and general election.[9]
- Continuous coverage of the epidemic over the past several years in national publications, including The New York Times,[10] The Washington Post,[11] The Wall Street Journal[12] and USA Today.[13]
- Seventy-three bills dealing with opioids have been introduced in the 115th Congress, including the Effective Opioid Enforcement Act, the DEA Opioid Enforcement Restoration Act, the Opioid Addiction Prevention Act and the Combating the Opioid Epidemic Act.[14]
- Concerns over the effect of cuts in Medicaid and resulting loss of access to opioid addiction treatment featured prominently in the debate over repeal of the Affordable Care Act.[15]
- Local budgets are being strained by the increase in opioid overdoses and hikes in the price of overdose reversal drug naloxone.[16]
- The opioid epidemic is taxing child welfare and foster care systems: Between 2013 and 2016, the number of children removed from their parents' care grew by 40%, driven mainly by opioid

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[5] http://www.cnn.com/2017/10/26/politics/donald-trump-opioid-epidemic/index.html

[6] https://www.whitehouse.gov/the-press-office/2017/03/30/presidential-executive-order-establishing-presidents-commission

[7] https://www.wsj.com/articles/drug-deaths-becoming-a-2016-presidential-election-issue-1446596075

[8] E.g., https://www.wsj.com/articles/drug-deaths-becoming-a-2016-presidential-election-issue-1446596075; http://www.cnn.com/2016/02/06/politics/donald-trump-new-hampshire-drug-epidemic/index.html

[9] E.g., https://web.archive.org/web/20170504001021/https://www.donaldjtrump.com/press-releases/donald-j.-trump-remarks-in-portsmouth-nh

[10] E.g., https://www.nytimes.com/2017/01/06/us/opioid-crisis-epidemic.html; https://www.nytimes.com/2017/10/26/us/opioid-crisis-public-health-emergency.html; https://www.nytimes.com/2017/08/21/health/hospitals-opioid-epidemic-patients.html; https://www.nytimes.com/2016/02/22/us/politics/governors-devise-bipartisan-effort-to-reduce-opioid-abuse.html; https://www.nytimes.com/2014/06/18/us/governors-unite-to-fight-heroin-in-new-england.html; https://www.nytimes.com/2015/01/13/us/after-stabilizing-overdose-deaths-rose-in-2013-.html.

[11] E.g., https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?tid=a_inl&utm_term=.84592cf7ad5d; https://www.washingtonpost.com/national/health-science/no-longer-mayberry-a-small-ohio-city-fights-an-epidemic-of-self-destruction/2016/12/29/a95076f2-9a01-11e6-b3c9-f662adaa0048_story.html?tid=sm_fb&utm_term=.91264e23e0fa; https://www.washingtonpost.com/news/to-your-health/wp/2017/03/?utm_term=.c6d46b0eeefe.

[12] E.g., http://www.wsj.com/graphics/toll-of-opioids/; https://www.wsj.com/articles/opioid-addiction-diagnoses-up-nearly-500-in-past-seven-years-study-shows-1498737603; https://www.wsj.com/articles/colleges-take-action-on-opioid-epidemic-1494158403?tesla=y; https://www.wsj.com/articles/the-children-of-the-opioid-crisis-1481816178.

[13] https://www.usatoday.com/story/news/politics/2017/10/23/fda-chief-supports-opioid-prescription-limits-regrets-agencys-prior-inaction/774007001/; https://www.usatoday.com/story/news/2017/11/08/its-far-more-than-overdoses-iv-opioid-users-diseases-overwhelm-hospitals/821693001/; https://www.usatoday.com/story/news/nation/2016/09/25/drug-addiction-treatment-insurance-heroin/91079496/;

[14] Data as of November 20, 2017 from Carol Nolan Drake, President and CEO, Carlow Consulting LLC (private correspondence dated November 20, 2017).

[15] E.g., http://www.latimes.com/politics/la-na-pol-obamacare-repeal-opioids-20170621-story.html; http://www.nejm.org/doi/full/10.1056/NEJMp1700834#t=article

[16] https://www.cnbc.com/2017/01/04/as-opioid-epidemic-worsens-the-cost-of-waking-up-from-an-overdose-soars.html; https://www.washingtonpost.com/world/as-opioid-overdoses-exact-a-higher-price-communities-ponder-who-should-be-saved/2017/07/15/1ea91890-67f3-11e7-8eb5-cbccc2e7bfbf_story.html?utm_term=.adb4f9214ba6.

addiction.[17] Several Ohio counties asked voters to approve ballot initiatives providing additional funding for family services in November 2017 due to opioid addiction.[18]

- Opioid use has been identified as a possible reason working-age men's participation in the labor force has been low.[19]
- The hospital costs associated with treating addicted newborns rose to $1.5 billion in 2013, from $732 million in 2009, according to a study in the Journal of Perinatology.[20] Stories like the one about James Schenk, born addicted to opioids, illustrate the difficulties of weaning these babies after birth.[21]

Mallinckrodt claims that manufacturers are too remote from physicians and patients to have a sufficiently strong nexus to the opioid crisis. But manufacturers of opioid medication have played an important role in creating and perpetuating the opioid crisis, and they are facing efforts to hold them accountable for their behavior, both legally and otherwise.

Numerous large cities, including Chicago, New York, Philadelphia and Seattle, and countless more small municipalities,[22] have sued opioid manufacturers in the past few years.[23] States[24] and counties[25] have done the same. Suits claim that manufacturers made misleading marketing claims, downplaying the risk of addiction and the efficacy of opioids for chronic pain, leading to opioid abuse and associated costs.[26] More than 250 cases have been consolidated in Ohio, where they are being overseen by Judge Dan Polster. Judge Polster has convened not only the parties in these cases, but others such as addiction experts, representatives of insurance companies, and officials of the FDA and DEA, with the goal of producing a settlement.[27]

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[17] https://www.wsj.com/articles/the-children-of-the-opioid-crisis-1481816178

[18] https://www.nytimes.com/aponline/2017/11/06/us/ap-us-opioid-crisis-children.html

[19] https://nypost.com/2017/07/23/yellen-links-opioid-crisis-to-low-workforce-participation/

[20] https://www.nytimes.com/2016/12/12/health/rise-in-infant-drug-dependence-in-us-is-felt-most-in-rural-areas.html

[21] http://host.madison.com/wsj/news/local/health-med-fit/babies-dependent-on-opioids-wisconsin-sees-surge-in-infants-born/article_1da6faee-827d-5435-aada-23a1d5fc8024.html

[22] http://hot96.com/news/articles/2018/feb/07/city-of-evansville-suing-opioid-manufacturers/

[23] https://www.citylab.com/life/2017/10/the-cities-suing-big-pharma-over-opioids/542484/; J. David Goodman & William Neuman, "New York City Sues Drug Companies Over Opioid Crisis," The New York Times, Jan. 23, 2018 (https://www.nytimes.com/2018/01/23/nyregion/nyc-de-blasio-opioid-lawsuit.html)

[24] https://www.theatlantic.com/business/archive/2017/06/lawsuit-pharmaceutical-companies-opioids/529020/; https://www.nbcphiladelphia.com/news/local/New-Jersey-Sues-Evil-Painkiller-Company-449651983.html; http://www.theadvocate.com/baton_rouge/news/crime_police/article_7c667572-02f8-11e8-ba90-53c92cef1f7c.html; https://www.google.com/search?q=opioid+manufacturers&ei=T_l8WtCKGYOO5wKyi5LgCw&start=30&sa=N&biw=1352&bih=693

[25] E.g., https://www.lohud.com/story/news/health/2018/02/06/westchester-targets-pharma-heroin-opioid-crisis-taxpayers/307951002/; http://www.islandpacket.com/news/local/article198598909.html; http://www.baltimoresun.com/news/maryland/baltimore-city/bs-md-ci-city-opioid-suit-20180131-story.html; http://www.syracuse.com/news/index.ssf/2018/01/onondaga_county_sues_drug_companies_over_opiod_crisis.html; http://www.gainesville.com/news/20180208/alachua-osceola-counties-take-aim-at-opioid-manufacturers

[26] J. David Goodman & William Neuman, "New York City Sues Drug Companies Over Opioid Crisis," The New York Times, Jan. 23, 2018 (https://www.nytimes.com/2018/01/23/nyregion/nyc-de-blasio-opioid-lawsuit.html); see also Rebecca L. Haffajee & Michelle M. Mello, "Drug Companies' Liability for the Opioid Epidemic," New England Journal of Medicine, Dec. 14, 2017 (http://www.nejm.org/doi/full/10.1056/NEJMp1710756)

[27] https://www.usnews.com/news/news/articles/2018-01-30/federal-judge-wants-opioid-lawsuits-to-end-in-settlement

Whether opioid manufacturers are ultimately held legally liable for various costs associated with the opioid crisis, they are being held responsible in the broader public debate about appropriate public policy responses and measures to deter opioid abuse. One article on the opioid crisis summed up this view as follows: "Managing pain, specifically chronic pain, is an essential part of any doctor's practice. It is terrible to see people suffer and whenever possible and prudent, pain should be treated. And some of the players in this story were driven by real concern for patients' quality of life. But others, specifically the manufacturers, were driven by crasser motives: the realization that they could make a fortune by pushing for wider use of prescription opioids."[28]

More specifically, drug manufacturers have been attacked for their promotion of opioid medications, both directly and indirectly. Materials provided to patients claimed that addiction was a "myth" and "rarely" occurred when opioids were prescribed for chronic pain. The PainKnowledge.com website, sponsored by Endo, made similar claims.[29] The study often cited in support of these assertions was very small, only 38 patients, and its author no longer stands behind it.[30]

The American Pain Foundation ("APF"), described in a 2011 ProPublica investigation as an "influential champion" for opioids, came under scrutiny early in the opioid crisis. The ProPublica investigation, published in the Washington Post,[31] revealed that the APF garnered nearly 90% of its funding in 2010 from the drug and medical device industry.[32] It also unearthed financial relationships between opioid manufacturers and APF board members.[33] Critics charged that it was serving as an ostensibly "patient-oriented" mouthpiece for opioid makers. The APF's publications were charged with being misleading and inappropriately downplaying the risks associated with opioids.[34] For example, the APF put out a publication sponsored by OxyContin manufacturer Purdue Pharma, asserting that only 1% of children prescribed opioids become addicted.[35]

In 2012, the Senate Finance Committee, as part of an investigation into drug manufacturers' responsibility for the opioid epidemic, wrote to the APF requesting information about funding of the APF by opioid manufacturers, collaborations between the APF and those funders and distribution of any publications written by opioid manufacturers.[36] The same day the letter was sent, the APF announced that it was immediately dissolving.[37]

A 2016 investigation by the Associated Press and Center for Public Integrity described a "pro-painkiller echo chamber" in Washington DC created by the Pain Care Forum ("PCF"), a "loose coalition of

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[28] http://www.slate.com/articles/health_and_science/medical_examiner/2016/06/prince_s_death_reveals_how_wrong_our_over_reliance_on_dangerous_opioids.html

[29] https://www.vox.com/policy-and-politics/2017/6/7/15724054/opioid-companies-epidemic-lawsuits

[30] http://www.slate.com/articles/health_and_science/medical_examiner/2016/06/prince_s_death_reveals_how_wrong_our_over_reliance_on_dangerous_opioids.html
https://www.wsj.com/articles/SB10001424127887324478304578173342657044604 (interview with study author Dr. Russell Portenoy)

[31] https://www.washingtonpost.com/national/health-science/patient-advocacy-group-funded-by-success-of-painkiller-drugs-probe-finds/2011/12/20/gIQAgvczDP_story.html?utm_term=.1c1e597c5206

[32] https://www.propublica.org/article/the-champion-of-painkillers

[33] https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry

[34] https://www.propublica.org/article/the-champion-of-painkillers

[35] https://www.vox.com/policy-and-politics/2017/6/7/15724054/opioid-companies-epidemic-lawsuits

[36] https://www.documentcloud.org/documents/354941-opioid-investigation-letter-to-american-pain.html

[37] https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups

drugmakers, trade groups and dozens of nonprofits supported by industry funding."[38] It was founded by the Washington lobbyists for Purdue Pharma, the OxyContin manufacturer that in 2007 settled claims of deceptive promotion of that drug. The investigation found that PCF participants spent massive amounts on lobbying, including on opioid-related matters, and political contributions.[39] The APF was "one of the [PCF's] principal members."[40] The PCF played a role in watering down the FDA's risk management plan around opioids, generating thousands of public comments.[41] Senator Ron Wyden raised concerns last year about the participation of industry-financed groups in an FDA workshop on opioid prescribing.[42]

Opioid manufacturers also influenced physicians through medical groups such as the American Pain Society ("APS") and the American Academy of Pain Medicine. Many fault these groups' increased emphasis on eliminating pain for contributing to the opioid crisis and trace the origin of that shift to the keynote address of the 1996 annual conference of the APS, which coined the phrase "the fifth vital sign" to encourage physicians to take pain management more seriously.[43] Purdue Pharma contributed funding to the APS during this time.[44]

Purdue also funded programs of the Joint Commission (formerly known as the Joint Commission on Accreditation of Healthcare Organizations) for complying with standards regarding pain management; the Joint Commission's 1999 pain policy stated that "Some clinicians have inaccurate and exaggerated concerns about addiction, tolerance and risk of death . . . despite the fact there is no evidence that addiction is a significant issue when persons are given opioids for pain control."[45] A CNN story from 2016 reported that the Joint Commission produced a book for use in continuing medical education, funded by Purdue, calling physician worries about opioid addiction "inaccurate and exaggerated."[46]

Similarly, a Purdue executive helped draft a 1998 policy from the Federation of State Medical Boards aimed at alleviating physician anxieties that they would be pursued by regulators for prescribing opioids; the Federation published an industry-funded book about the policy, pocketing the proceeds.[47]

Reviewing the history of the opioid abuse crisis, an article in the Cleveland Clinic Journal of Medicine explained the role of manufacturers: "Opportunistically, or perhaps wielding inappropriate and

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[38] https://www.apnews.com/3d257452c24a410f98e8e5a4d9d448a7
[39] https://www.apnews.com/3d257452c24a410f98e8e5a4d9d448a7
[40] https://www.apnews.com/3d257452c24a410f98e8e5a4d9d448a7
[41] https://www.apnews.com/3d257452c24a410f98e8e5a4d9d448a7
[42] https://www.finance.senate.gov/imo/media/doc/050517%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group.pdf
http://www.modernhealthcare.com/article/20170508/NEWS/170509883
[43] https://www.vox.com/2017/6/5/15111936/opioid-crisis-pain-west-virginia;
http://www.slate.com/articles/health_and_science/medical_examiner/2016/06/prince_s_death_reveals_how_wrong_our_over_reliance_on_dangerous_opioids.html
[44] https://www.vox.com/2017/6/5/15111936/opioid-crisis-pain-west-virginia
[45] http://www.slate.com/articles/health_and_science/medical_examiner/2016/06/prince_s_death_reveals_how_wrong_our_over_reliance_on_dangerous_opioids.html
[46] https://www.cnn.com/2016/05/12/health/opioid-addiction-history/
[47] https://www.wsj.com/articles/SB10001424127887324478304578173342657044604

sketchy influence, some drug manufacturers in the early 2000s funded publications and physician presentations to encourage the expanded use of opioids and other medications for pain control."[48]

In September 2017, forty-one attorneys general wrote to America's Health Insurance Plans ("AHIP"), the trade association for health insurers, asking it to "encourage [its] members to review their payment and coverage policies . . . to encourage healthcare providers to prioritize non-opioid pain management options over opioid prescriptions for the treatment of chronic, non-cancer pain."[49] AHIP launched the Safe, Transparent Opioid Prescribing ("STOP") Initiative, which is "designed to support widespread adoption of clinical guidelines for pain care and opioid prescribing," a month later.[50] As part of STOP, AHIP released the STOP Measure, which allows plans to compare physician prescribing practices to the Centers for Disease Control ("CDC") Guideline for Prescribing Opioids for Chronic Pain. [51]

The CDC Guideline was released in March 2016, after a notice and comment process, to help physicians decide whether to prescribe opioids and to provide advice on "medication selection, dosage, duration and discontinuation of treatment."[52] An article in JAMA Internal Medicine reviewed the comments submitted on the Guideline and found that, among the 150 organizations that submitted comments, opposition to the Guideline was associated with having received funding from opioid manufacturers, as was opposition specifically to the recommendations about dosing and duration of treatment.[53]

The Senate's Homeland Security and Governmental Affairs Committee opened an investigation in Mar. 2017 into the makers of the five opioid medications with the highest sales.[54] The investigation sought to determine "whether pharmaceutical manufacturers—at the head of the opioids pipeline—have contributed to opioid over-utilization and over-prescription . . . ." [55] Senator Claire McCaskill, in her letter to the manufacturers, who did not include Mallinckrodt, opined that the opioid epidemic "is the direct result of a calculated sales and marketing strategy major opioid manufacturers have allegedly pursued over the past 20 years to expand their market share and increase dependency on powerful — and often deadly — painkillers."[56] Specifically, she wrote, manufacturers "downplay[ed] the risk of addition"

In sum, the opioid abuse crisis is one of the most urgent social problems facing the U.S., with major effects on health, prosperity and well-being. Significant attention and criticism have focused on opioid manufacturers for deceptively promoting opioids, inappropriately intervening the legislative and political process and influencing physician prescribing, both directly and indirectly, through trade associations and other groups. Accordingly, the subject of the Proposal—how Mallinckrodt has changed its corporate

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[48] https://www.mdedge.com/ccjm/article/109138/drug-therapy/fifth-vital-sign-complex-story-politics-and-patient-care

[49] http://myfloridalegal.com/webfiles.nsf/WF/JMAR-ARCKCD/$file/NAAG-Opioid-Letter-to-AHIP.pdf

[50] https://www.ahip.org/health-plans-launch-new-stop-initiative-to-help-battle-opioid-crisis-in-america/

[51] https://www.ahip.org/health-plans-launch-new-stop-initiative-to-help-battle-opioid-crisis-in-america/

[52] https://www.cdc.gov/media/releases/2016/p0315-prescribing-opioids-guidelines.html

[53] https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2598092?redirect=true

[54] Dan Mangan, "Opioid Epidemic: Senate Committee Opens Probe of Five Big Painkiller Makers," CNBC, Mar. 28, 2017 (https://www.cnbc.com/2017/03/28/senate-committee-opens-probe-of-five-big-opioid-makers.html); https://www.motherjones.com/politics/2017/03/opioid-investigation-mccaskill-pharmaceutical-companies/

[55] Dan Mangan, "Opioid Epidemic: Senate Committee Opens Probe of Five Big Painkiller Makers," CNBC, Mar. 28, 2017 (https://www.cnbc.com/2017/03/28/senate-committee-opens-probe-of-five-big-opioid-makers.html)

[56] Dan Mangan, "Opioid Epidemic: Senate Committee Opens Probe of Five Big Painkiller Makers," CNBC, Mar. 28, 2017 (https://www.cnbc.com/2017/03/28/senate-committee-opens-probe-of-five-big-opioid-makers.html)

governance to monitor and manage opioid-related risks—is a significant social policy issue with a strong connection to Mallinckrodt.

The "Sale of Products" Determinations Do Not Apply Because the Proposal Deals with a Significant Social Policy Issue

Mallinckrodt rests its argument on previous determinations in which the Staff permitted companies that sold or distributed products to exclude proposals related to those products on ordinary business grounds. The proposals in those determinations, which fall into three categories, differ from the Proposal in important ways. Mallinckrodt also neglected to mention a recent determination declining to allow exclusion on ordinary business grounds of a proposal nearly identical to the Proposal submitted at a pharmaceutical distributor.

First, Mallinckrodt points to proposals submitted last year to AbbVie[57] and Johnson & Johnson,[58] which asked those companies to report on their policies for safe disposal of prescription drugs to prevent water pollution and possible options to address that problem, including the endorsement or funding of industry take-back programs. Both AbbVie and Johnson & Johnson argued, among other things, that the proposals dealt with their ordinary business operations, urging that they addressed customer disposal and misuse of their products. The Staff concurred with the companies' positions, stating simply that the proposals related to the companies' ordinary business operations.

The Staff thus implicitly rejected the proponents' claims that the proposals dealt with a significant social policy issue. In opposing the Johnson & Johnson no-action request, the proponent had argued that the proposals addressed "the significant public policy issue of reducing water pollution caused by disposal of used pharmaceuticals." In responding to both requests, the proponents had attempted to tie the take-back issue to the larger problem of the opioid crisis.

The AbbVie and Johnson & Johnson determinations are not dispositive here, however, because the connection to the opioid crisis was more remote in those proposals. Both proposals' supporting statements addressed concerns over water pollution in addition to the possibility of poisoning or opioid misuse resulting from the lack of safe disposal options for leftover opioid medications. The public debate described in the Johnson & Johnson no-action response related almost entirely to take-back programs.

The AbbVie and Johnson & Johnson proposals' supporting statements also discussed the mechanics and funding of take-back programs for prescription drugs and other hazardous products. In that way, the AbbVie and Johnson & Johnson proposals were much more operationally focused than the Proposal, which confines its scope to governance measures aimed at better managing opioid-related risks. Unlike the proposals in AbbVie and Johnson & Johnson, the Proposal does not concern itself with specific product-related practices.

The second group of determinations on which Mallinckrodt relies involve proposals submitted to distributors or retailers, but not manufacturers, addressing risks related to the sale or distribution of controversial products such as tobacco, firearms and products tested on animals, which were deemed excludable on ordinary business grounds.[59] Although the reasoning for those determinations is not provided, it is possible to infer that the Staff believed that the proposal subjects did not qualify as significant

[57] AbbVie Inc. (Mar. 16, 2017)

[58] Johnson & Johnson (Jan. 30, 2017)

[59] See determinations cited on pages 4-6 of the No-Action Request.

social policy issues or that a sufficient nexus did not exist between the companies, whose involvement with the products was essentially passive, and the policy issues associated with the products themselves.

Mallinckrodt also cites two determinations allowing omission of proposals at drug manufacturers Pfizer[60] (drugs used in executions) and Eli Lilly[61] (price increases on specific drugs). As with the proposals described above, it appears likely that the Staff did not view the issues raised by the proposals as significant social policy issues, given that the nexus between the companies and issues was strong.

The Staff's recent determination in AmerisourceBergen Corporation,[62] on a proposal nearly identical to the Proposal, supports our contention that the opioid crisis is a significant social policy issue and was not mentioned by Mallinckrodt. In that determination, the Staff rejected a drug distributor's argument that the required nexus between the opioid crisis and the company's activities as a distributor did not exist. If the nexus is strong enough for a distributor, manufacturers, who are blamed equally, if not more, for opioid misuse, must have a sufficiently strong nexus.

Mallinckrodt's protestation that "[o]pioid products account for only a small portion—less than 10%--of Mallinckrodt's total revenues" does not undermine the strength of the nexus. Companies sometimes use a "rule of thumb" that a misstatement or omission is material if it involves 5% or more of revenues, though the Staff has indicated that solely using a numeric threshold is inappropriate.[63] As well, under the recent Staff Legal Bulletin 14I,[64] an argument like this one about nexus should be part of a submission reflecting the board's consideration of the Proposal's subject in the context of the company's business. The absence of such a submission substantially weakens Mallinckrodt's argument.

The Proposal's Subject is Not Mallinckrodt's Compliance Program

Mallinckrodt also contends that the Proposal's topic is the Company's compliance program, citing determinations that have permitted omission on ordinary business grounds of proposals addressing legal compliance. That claim is inconsistent with the actual language of the Proposal and ignores the fact that the Proposal deals with a significant social policy issue.

Unlike the numerous determinations discussed on page six of the No-Action Request, the Proposal does not ask for reporting on how Mallinckrodt is ensuring compliance with a specific law or adoption of a new policy aimed at improving compliance. Potential liability stemming from culpability in the opioid crisis forms the backdrop for the Proposal, but is not the Proposal's primary thrust. Instead, the Proposal focuses on governance measures to manage risk going forward.

It is worth noting that even a proposal focused more directly on compliance is not excludable if the subject qualifies as a significant social policy issue. For example, the Commission has stated that "significant employment discrimination matters," which by their nature involve legal compliance, are a significant social policy issue.[65] Here, given that the opioid crisis is a significant social policy issue, the remote connection between the Proposal and legal compliance does not support exclusion.

The Proposal Would Not Micromanage Mallinckrodt

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[60] Pfizer Inc. (Mar. 1, 2016)
[61] Eli Lilly and Company (Feb. 10, 2017)
[62] AmerisourceBergen Corporation (Jan. 11, 2018)
[63] Staff Accounting Bulletin No. 99, "Materiality" (Aug. 12, 1999)
[64] Staff Legal Bulletin 14I (Nov. 1, 2017)
[65] Exchange Act Release No. 40018 (May 21, 1998)

The Commission has articulated the two "central considerations" animating the ordinary business exclusion:

1. "Certain tasks are so fundamental to management's ability to run a company on a day-to-day basis that they could not, as a practical matter, be subject to direct shareholder oversight"; and

2. "the degree to which the proposal seeks to 'micro-manage' the company by probing too deeply into matters of a complex nature upon which shareholders, as a group, would not be in a position to make an informed judgment."[66]

Mallinckrodt urges that the Proposal would micromanage it because it seeks to control "decisions regarding the manufacture and sale of particular products, compliance with laws and regulations and its allocation of capital resources."[67]

Unlike the proposals in many of the determinations cited by Mallinckrodt, the Proposal does not seek to control which products Mallinckrodt distributes, but rather asks for a single report to shareholders. We acknowledge that allowing shareholders to make day-to-day decisions about product selection would be impractical and undesirable. Nor does the Proposal ask for detailed reporting or operational changes related to a technical subject, as the proposals in Ford Motor Co.[68] and Marriott International[69] did.

Mallinckrodt also urges that the Proposal would require disclosure of complex information that would be difficult for shareholders to understand. There is no support in the Proposal for Mallinckrodt's claim that it seeks disclosure about "the decisions necessary to manage its ordinary business of producing and selling opioid-containing products while attempting to minimize harm associated with potential diversion and misuse of such products."[70]

The kinds of governance measures discussed in the Proposal—board oversight of risk, compensation metrics, stakeholder engagement and political activity policies—are the subject of shareholder proposals on which shareholders frequently cast votes, and companies themselves often make significant amounts of disclosure on these governance arrangements. The Proposal does not even urge the adoption of any particular governance measure, but only asks for reporting on what Mallinckrodt has already done. Accordingly, the Proposal cannot be said to micromanage Mallinckrodt.

Substantial Implementation

Mallinckrodt contends it has substantially implemented the Proposal through its existing disclosures. First, Mallinckrodt points to its website disclosure regarding anti-diversion efforts and disclosure in its annual report regarding compliance and anti-diversion programs. None of those disclosures is responsive to the Proposal, which focuses on governance rather than operational measures.

Mallinckrodt also argues that it has substantially implemented the Proposal's request for disclosure of board oversight of opioid-related risks. Mallinckrodt asserts that the Company's 2017 proxy statement "describes the committees of the Board and their and management's roles in regularly reviewing and monitoring key risks, including financial and reputational risks related to the sale of opioid-containing

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[66] Exchange Act Release No. 40018 (May 21, 1998)

[67] No-Action Request, at 11

[68] Ford Motor Company (Mar. 2, 2004)

[69] Marriott International Inc. (Mar. 17, 2010)

[70] No-Action Request, at 12

products."[71] But the terms "opioid" and "controlled substance" do not appear in the Company's proxy statement. The No-Action Request refers obliquely to Mallinckrodt's Corporate Governance Guidelines and board committee charters, but the Corporate Governance Guidelines, Compliance Committee Charter and Audit Committee Charter are all silent on both opioids and controlled substances.

Mallinckrodt would apparently like shareholders to infer that references to risk and compliance in the Company's governance documents encompass opioid-related matters. There is no reason for shareholders to make those assumptions, though. The purpose of the Proposal is to obtain information about governance measures that Mallinckrodt affirmatively states are intended to help the Company more effectively manage opioid-related risks. Disclosures that refer generically to risk or compliance do not provide the requested information. If indeed opioid-related risks are simply lumped in with other risks, with no special governance mechanisms or considerations, then Mallinckrodt could substantially implement the Proposal by saying so. Its current disclosures, however, fall far short.

* * *

For the reasons set forth above, Mallinckrodt has not met its burden of showing that it is entitled to omit the Proposal in reliance on Rule 14a-8(i)(7) or Rule 14a-8(i)(10). The Proponents thus respectfully request that Mallinckrodt's request for relief be denied.

The Proponents appreciate the opportunity to be of assistance in this matter. If you have any questions or need additional information, please contact me at (513) 673-9992 or Donna Meyer, Director of Shareholder Advocacy, (713) 299-5018, dmeyer@mercyinvestments.org.

Sincerely,

Susan S. Makos

Susan S. Makos, JD
Vice President of Social Responsibility
Mercy Investment Services, Inc.
smakos@mercyinvestments.org

cc: Victor Goldfeld
VGoldfeld@wlrk.com

[71] No-Action Request, at 14

February 9, 2018

Via e-mail at shareholderproposals@sec.gov

Securities and Exchange Commission
Office of the Chief Counsel
Division of Corporation Finance
100 F Street, NE
Washington, DC 20549

Re: Request by Mallinckrodt plc to omit proposal submitted by Mercy Investment Services, Providence Trust and co-filers

Ladies and Gentlemen,

Pursuant to Rule 14a-8 under the Securities Exchange Act of 1934, Mercy Investment Services Inc., Providence Trust and Catholic Health Initiatives (together, the "Proponents") submitted a shareholder proposal (the "Proposal") to Mallinckrodt plc ("Mallinckrodt" or the "Company"). The Proposal asks Mallinckrodt's board to report to shareholders on governance measures ABC has implemented since 2012 to more effectively monitor and manage financial and reputational risks related to the opioid crisis in the U.S.

In a letter to the Division dated January 12, 2018 (the "No-Action Request"), Mallinckrodt stated that it intends to omit the Proposal from its proxy materials to be distributed to shareholders in connection with the Company's 2018 annual meeting of shareholders. Mallinckrodt argues that it is entitled to exclude the Proposal in reliance on Rule 14a-8(i)(7), as relating to Mallinckrodt's ordinary business operations; and Rule 14a-8(i)(10), on the ground that Mallinckrodt has substantially implemented the Proposal. As discussed more fully below, Mallinckrodt has not met its burden of proving its entitlement to rely on either exclusion; accordingly, the Proponents respectfully ask that the Company's request for relief be denied.

The Proposal

The Proposal states:

"RESOLVED, that shareholders of Mallinckrodt plc ("Mallinckrodt") urge the Board of Directors (the "Board") to report to shareholders by September 30, 2018 on the governance measures Mallinckrodt has implemented since 2012 to more effectively monitor and manage financial and reputational risks related to the opioid crisis in the U.S., given Mallinckrodt's sale of opioid medications and active

pharmaceutical ingredients in opioid medications, including whether Mallinckrodt has assigned responsibility for such monitoring to the Board or one or more Board committees, revised senior executive compensation metrics or policies, adopted or changed mechanisms for obtaining input from stakeholders, or altered policies or processes regarding company political activities.

The report should be prepared at reasonable cost and should omit confidential and proprietary information."

Ordinary Business

Mallinckrodt argues that it is entitled to omit the Proposal in reliance on Rule 14a-8(i)(7), which allows exclusion of proposals related to a company's ordinary business operations. Specifically, Mallinckrodt urges that the Proposal's subject is the "manufacture and sale of products" or the Company's compliance program and that the Proposal does not deal with a significant social policy issue with a nexus to Mallinckrodt. Mallinckrodt also claims the Proposal would micromanage the Company.

As discussed below, Mallinckrodt has not met its burden of establishing that the Proposal relates to its ordinary business operations. The Proposal addresses a significant social policy issue with which opioid manufacturers have a strong connection. The Proposal asks for disclosure of governance measures, not a specific policy change or detailed reporting about operations, and thus cannot be said to micromanage Mallinckrodt. Accordingly, the Proponents ask that Mallinckrodt's request for relief be denied.

The Opioid Crisis Is a Significant Social Policy Issue and a Strong Nexus to Opioid Manufacturers Exists

The opioid epidemic is undoubtedly a "sustained" and "consistent topic of widespread public debate," the standard the Staff has applied in determining whether a proposal deals with a significant social policy issue.[1]

According to the Center for Disease Control and Prevention ("CDC"), the number of opioid painkillers dispensed in the U.S. quadrupled from 1999 to 2010, despite no change in reported pain levels.[2] In 2015, opioid overdoses killed more than 33,000 Americans, and that number is expected to be up significantly when official data for 2016 are released.[3] Opioid addiction alone has lowered U.S. average life expectancy by 2.5 months.[4]

The sheer volume of national media coverage, expressions of public sentiment and legislative and regulatory initiatives spawned by the opioid epidemic precludes an exhaustive list. Some key examples are:

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[1] See Exchange Act Release No. 40018 (May 21, 1998); Comcast Corp. (Mar. 4, 2011); Verizon Communications Inc. (Feb. 13, 2012).

[2] https://www.cdc.gov/drugoverdose/epidemic/index.html.

[3] Centers for Disease Control and Prevention data on 2015 deaths (https://www.cdc.gov/drugoverdose/); Lenny Bernstein, "Deaths from Drug Overdoses Soared in the First Nine Months of 2016," The Washington Post, Aug. 8, 2017 (https://www.washingtonpost.com/news/to-your-health/wp/2017/08/08/deaths-from-drug-overdoses-soared-in-the-first-nine-months-of-2016/) ("Given available state data and anecdotal information, many experts are expecting a big increase in deaths in 2016, driven by the worsening crisis in overdoses from opioids, especially fentanyl and heroin").

[4] http://www.chicagotribune.com/news/nationworld/ct-opioids-life-expectancy-20170920-story.html

- President Trump declared the opioid epidemic a public health emergency in October 2017.[5] He has empaneled a Presidential Commission on Combating Addiction and the Opioid Crisis to make recommendations on the federal response.[6]
- During the 2016 Presidential election campaign, addressing the opioid crisis ranked as the most important issue for voters in some areas.[7] Candidates discussed the opioid epidemic on the campaign trail in both the primaries[8] and general election.[9]
- Continuous coverage of the epidemic over the past several years in national publications, including The New York Times,[10] The Washington Post,[11] The Wall Street Journal[12] and USA Today.[13]
- Seventy-three bills dealing with opioids have been introduced in the 115th Congress, including the Effective Opioid Enforcement Act, the DEA Opioid Enforcement Restoration Act, the Opioid Addiction Prevention Act and the Combating the Opioid Epidemic Act.[14]
- Concerns over the effect of cuts in Medicaid and resulting loss of access to opioid addiction treatment featured prominently in the debate over repeal of the Affordable Care Act.[15]
- Local budgets are being strained by the increase in opioid overdoses and hikes in the price of overdose reversal drug naloxone.[16]
- The opioid epidemic is taxing child welfare and foster care systems: Between 2013 and 2016, the number of children removed from their parents' care grew by 40%, driven mainly by opioid

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[5] http://www.cnn.com/2017/10/26/politics/donald-trump-opioid-epidemic/index.html

[6] https://www.whitehouse.gov/the-press-office/2017/03/30/presidential-executive-order-establishing-presidents-commission

[7] https://www.wsj.com/articles/drug-deaths-becoming-a-2016-presidential-election-issue-1446596075

[8] E.g., https://www.wsj.com/articles/drug-deaths-becoming-a-2016-presidential-election-issue-1446596075; http://www.cnn.com/2016/02/06/politics/donald-trump-new-hampshire-drug-epidemic/index.html

[9] E.g., https://web.archive.org/web/20170504001021/https://www.donaldjtrump.com/press-releases/donald-j.-trump-remarks-in-portsmouth-nh

[10] E.g., https://www.nytimes.com/2017/01/06/us/opioid-crisis-epidemic.html; https://www.nytimes.com/2017/10/26/us/opioid-crisis-public-health-emergency.html; https://www.nytimes.com/2017/08/21/health/hospitals-opioid-epidemic-patients.html; https://www.nytimes.com/2016/02/22/us/politics/governors-devise-bipartisan-effort-to-reduce-opioid-abuse.html; https://www.nytimes.com/2014/06/18/us/governors-unite-to-fight-heroin-in-new-england.html; https://www.nytimes.com/2015/01/13/us/after-stabilizing-overdose-deaths-rose-in-2013-.html.

[11] E.g., https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?tid=a_inl&utm_term=.84592cf7ad5d; https://www.washingtonpost.com/national/health-science/no-longer-mayberry-a-small-ohio-city-fights-an-epidemic-of-self-destruction/2016/12/29/a95076f2-9a01-11e6-b3c9-f662adaa0048_story.html?tid=sm_fb&utm_term=.91264e23e0fa; https://www.washingtonpost.com/news/to-your-health/wp/2017/03/?utm_term=.c6d46b0eeefe.

[12] E.g., http://www.wsj.com/graphics/toll-of-opioids/; https://www.wsj.com/articles/opioid-addiction-diagnoses-up-nearly-500-in-past-seven-years-study-shows-1498737603; https://www.wsj.com/articles/colleges-take-action-on-opioid-epidemic-1494158403?tesla=y; https://www.wsj.com/articles/the-children-of-the-opioid-crisis-1481816178.

[13] https://www.usatoday.com/story/news/politics/2017/10/23/fda-chief-supports-opioid-prescription-limits-regrets-agencys-prior-inaction/774007001/; https://www.usatoday.com/story/news/2017/11/08/its-far-more-than-overdoses-iv-opioid-users-diseases-overwhelm-hospitals/821693001/; https://www.usatoday.com/story/news/nation/2016/09/25/drug-addiction-treatment-insurance-heroin/91079496/;

[14] Data as of November 20, 2017 from Carol Nolan Drake, President and CEO, Carlow Consulting LLC (private correspondence dated November 20, 2017).

[15] E.g., http://www.latimes.com/politics/la-na-pol-obamacare-repeal-opioids-20170621-story.html; http://www.nejm.org/doi/full/10.1056/NEJMp1700834#t=article

[16] https://www.cnbc.com/2017/01/04/as-opioid-epidemic-worsens-the-cost-of-waking-up-from-an-overdose-soars.html; https://www.washingtonpost.com/world/as-opioid-overdoses-exact-a-higher-price-communities-ponder-who-should-be-saved/2017/07/15/1ea91890-67f3-11e7-8eb5-cbccc2e7bfbf_story.html?utm_term=.adb4f9214ba6.

addiction.[17] Several Ohio counties asked voters to approve ballot initiatives providing additional funding for family services in November 2017 due to opioid addiction.[18]

- Opioid use has been identified as a possible reason working-age men's participation in the labor force has been low.[19]
- The hospital costs associated with treating addicted newborns rose to $1.5 billion in 2013, from $732 million in 2009, according to a study in the Journal of Perinatology.[20] Stories like the one about James Schenk, born addicted to opioids, illustrate the difficulties of weaning these babies after birth.[21]

Mallinckrodt claims that manufacturers are too remote from physicians and patients to have a sufficiently strong nexus to the opioid crisis. But manufacturers of opioid medication have played an important role in creating and perpetuating the opioid crisis, and they are facing efforts to hold them accountable for their behavior, both legally and otherwise.

Numerous large cities, including Chicago, New York, Philadelphia and Seattle, and countless more small municipalities,[22] have sued opioid manufacturers in the past few years.[23] States[24] and counties[25] have done the same. Suits claim that manufacturers made misleading marketing claims, downplaying the risk of addiction and the efficacy of opioids for chronic pain, leading to opioid abuse and associated costs.[26] More than 250 cases have been consolidated in Ohio, where they are being overseen by Judge Dan Polster. Judge Polster has convened not only the parties in these cases, but others such as addiction experts, representatives of insurance companies, and officials of the FDA and DEA, with the goal of producing a settlement.[27]

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[17] https://www.wsj.com/articles/the-children-of-the-opioid-crisis-1481816178

[18] https://www.nytimes.com/aponline/2017/11/06/us/ap-us-opioid-crisis-children.html

[19] https://nypost.com/2017/07/23/yellen-links-opioid-crisis-to-low-workforce-participation/

[20] https://www.nytimes.com/2016/12/12/health/rise-in-infant-drug-dependence-in-us-is-felt-most-in-rural-areas.html

[21] http://host.madison.com/wsj/news/local/health-med-fit/babies-dependent-on-opioids-wisconsin-sees-surge-in-infants-born/article_1da6faee-827d-5435-aada-23a1d5fc8024.html

[22] http://hot96.com/news/articles/2018/feb/07/city-of-evansville-suing-opioid-manufacturers/

[23] https://www.citylab.com/life/2017/10/the-cities-suing-big-pharma-over-opioids/542484/; J. David Goodman & William Neuman, "New York City Sues Drug Companies Over Opioid Crisis," The New York Times, Jan. 23, 2018 (https://www.nytimes.com/2018/01/23/nyregion/nyc-de-blasio-opioid-lawsuit.html)

[24] https://www.theatlantic.com/business/archive/2017/06/lawsuit-pharmaceutical-companies-opioids/529020/; https://www.nbcphiladelphia.com/news/local/New-Jersey-Sues-Evil-Painkiller-Company-449651983.html; http://www.theadvocate.com/baton_rouge/news/crime_police/article_7c667572-02f8-11e8-ba90-53c92cef1f7c.html; https://www.google.com/search?q=opioid+manufacturers&ei=T_l8WtCKGYOO5wKyi5LgCw&start=30&sa=N&biw=1352&bih=693

[25] E.g., https://www.lohud.com/story/news/health/2018/02/06/westchester-targets-pharma-heroin-opioid-crisis-taxpayers/307951002/; http://www.islandpacket.com/news/local/article198598909.html; http://www.baltimoresun.com/news/maryland/baltimore-city/bs-md-ci-city-opioid-suit-20180131-story.html; http://www.syracuse.com/news/index.ssf/2018/01/onondaga_county_sues_drug_companies_over_opiod_crisis.html; http://www.gainesville.com/news/20180208/alachua-osceola-counties-take-aim-at-opioid-manufacturers

[26] J. David Goodman & William Neuman, "New York City Sues Drug Companies Over Opioid Crisis," The New York Times, Jan. 23, 2018 (https://www.nytimes.com/2018/01/23/nyregion/nyc-de-blasio-opioid-lawsuit.html); see also Rebecca L. Haffajee & Michelle M. Mello, "Drug Companies' Liability for the Opioid Epidemic," New England Journal of Medicine, Dec. 14, 2017 (http://www.nejm.org/doi/full/10.1056/NEJMp1710756)

[27] https://www.usnews.com/news/news/articles/2018-01-30/federal-judge-wants-opioid-lawsuits-to-end-in-settlement

Whether opioid manufacturers are ultimately held legally liable for various costs associated with the opioid crisis, they are being held responsible in the broader public debate about appropriate public policy responses and measures to deter opioid abuse. One article on the opioid crisis summed up this view as follows: "Managing pain, specifically chronic pain, is an essential part of any doctor's practice. It is terrible to see people suffer and whenever possible and prudent, pain should be treated. And some of the players in this story were driven by real concern for patients' quality of life. But others, specifically the manufacturers, were driven by crasser motives: the realization that they could make a fortune by pushing for wider use of prescription opioids."[28]

More specifically, drug manufacturers have been attacked for their promotion of opioid medications, both directly and indirectly. Materials provided to patients claimed that addiction was a "myth" and "rarely" occurred when opioids were prescribed for chronic pain. The PainKnowledge.com website, sponsored by Endo, made similar claims.[29] The study often cited in support of these assertions was very small, only 38 patients, and its author no longer stands behind it.[30]

The American Pain Foundation ("APF"), described in a 2011 ProPublica investigation as an "influential champion" for opioids, came under scrutiny early in the opioid crisis. The ProPublica investigation, published in the Washington Post,[31] revealed that the APF garnered nearly 90% of its funding in 2010 from the drug and medical device industry.[32] It also unearthed financial relationships between opioid manufacturers and APF board members.[33] Critics charged that it was serving as an ostensibly "patient-oriented" mouthpiece for opioid makers. The APF's publications were charged with being misleading and inappropriately downplaying the risks associated with opioids.[34] For example, the APF put out a publication sponsored by OxyContin manufacturer Purdue Pharma, asserting that only 1% of children prescribed opioids become addicted.[35]

In 2012, the Senate Finance Committee, as part of an investigation into drug manufacturers' responsibility for the opioid epidemic, wrote to the APF requesting information about funding of the APF by opioid manufacturers, collaborations between the APF and those funders and distribution of any publications written by opioid manufacturers.[36] The same day the letter was sent, the APF announced that it was immediately dissolving.[37]

A 2016 investigation by the Associated Press and Center for Public Integrity described a "pro-painkiller echo chamber" in Washington DC created by the Pain Care Forum ("PCF"), a "loose coalition of

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[28] http://www.slate.com/articles/health_and_science/medical_examiner/2016/06/prince_s_death_reveals_how_wrong_our_over_reliance_on_dangerous_opioids.html

[29] https://www.vox.com/policy-and-politics/2017/6/7/15724054/opioid-companies-epidemic-lawsuits

[30] http://www.slate.com/articles/health_and_science/medical_examiner/2016/06/prince_s_death_reveals_how_wrong_our_over_reliance_on_dangerous_opioids.html
https://www.wsj.com/articles/SB10001424127887324478304578173342657044604 (interview with study author Dr. Russell Portenoy)

[31] https://www.washingtonpost.com/national/health-science/patient-advocacy-group-funded-by-success-of-painkiller-drugs-probe-finds/2011/12/20/gIQAgvczDP_story.html?utm_term=.1c1e597c5206

[32] https://www.propublica.org/article/the-champion-of-painkillers

[33] https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry

[34] https://www.propublica.org/article/the-champion-of-painkillers

[35] https://www.vox.com/policy-and-politics/2017/6/7/15724054/opioid-companies-epidemic-lawsuits

[36] https://www.documentcloud.org/documents/354941-opioid-investigation-letter-to-american-pain.html

[37] https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups

drugmakers, trade groups and dozens of nonprofits supported by industry funding."[38] It was founded by the Washington lobbyists for Purdue Pharma, the OxyContin manufacturer that in 2007 settled claims of deceptive promotion of that drug. The investigation found that PCF participants spent massive amounts on lobbying, including on opioid-related matters, and political contributions.[39] The APF was "one of the [PCF's] principal members."[40] The PCF played a role in watering down the FDA's risk management plan around opioids, generating thousands of public comments.[41] Senator Ron Wyden raised concerns last year about the participation of industry-financed groups in an FDA workshop on opioid prescribing.[42]

Opioid manufacturers also influenced physicians through medical groups such as the American Pain Society ("APS") and the American Academy of Pain Medicine. Many fault these groups' increased emphasis on eliminating pain for contributing to the opioid crisis and trace the origin of that shift to the keynote address of the 1996 annual conference of the APS, which coined the phrase "the fifth vital sign" to encourage physicians to take pain management more seriously.[43] Purdue Pharma contributed funding to the APS during this time.[44]

Purdue also funded programs of the Joint Commission (formerly known as the Joint Commission on Accreditation of Healthcare Organizations) for complying with standards regarding pain management; the Joint Commission's 1999 pain policy stated that "Some clinicians have inaccurate and exaggerated concerns about addiction, tolerance and risk of death . . . despite the fact there is no evidence that addiction is a significant issue when persons are given opioids for pain control."[45] A CNN story from 2016 reported that the Joint Commission produced a book for use in continuing medical education, funded by Purdue, calling physician worries about opioid addiction "inaccurate and exaggerated."[46]

Similarly, a Purdue executive helped draft a 1998 policy from the Federation of State Medical Boards aimed at alleviating physician anxieties that they would be pursued by regulators for prescribing opioids; the Federation published an industry-funded book about the policy, pocketing the proceeds.[47]

Reviewing the history of the opioid abuse crisis, an article in the Cleveland Clinic Journal of Medicine explained the role of manufacturers: "Opportunistically, or perhaps wielding inappropriate and

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[38] https://www.apnews.com/3d257452c24a410f98e8e5a4d9d448a7
[39] https://www.apnews.com/3d257452c24a410f98e8e5a4d9d448a7
[40] https://www.apnews.com/3d257452c24a410f98e8e5a4d9d448a7
[41] https://www.apnews.com/3d257452c24a410f98e8e5a4d9d448a7
[42] https://www.finance.senate.gov/imo/media/doc/050517%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group.pdf
http://www.modernhealthcare.com/article/20170508/NEWS/170509883
[43] https://www.vox.com/2017/6/5/15111936/opioid-crisis-pain-west-virginia;
http://www.slate.com/articles/health_and_science/medical_examiner/2016/06/prince_s_death_reveals_how_wrong_our_over_reliance_on_dangerous_opioids.html
[44] https://www.vox.com/2017/6/5/15111936/opioid-crisis-pain-west-virginia
[45] http://www.slate.com/articles/health_and_science/medical_examiner/2016/06/prince_s_death_reveals_how_wrong_our_over_reliance_on_dangerous_opioids.html
[46] https://www.cnn.com/2016/05/12/health/opioid-addiction-history/
[47] https://www.wsj.com/articles/SB10001424127887324478304578173342657044604

sketchy influence, some drug manufacturers in the early 2000s funded publications and physician presentations to encourage the expanded use of opioids and other medications for pain control."[48]

In September 2017, forty-one attorneys general wrote to America's Health Insurance Plans ("AHIP"), the trade association for health insurers, asking it to "encourage [its] members to review their payment and coverage policies . . . to encourage healthcare providers to prioritize non-opioid pain management options over opioid prescriptions for the treatment of chronic, non-cancer pain."[49] AHIP launched the Safe, Transparent Opioid Prescribing ("STOP") Initiative, which is "designed to support widespread adoption of clinical guidelines for pain care and opioid prescribing," a month later.[50] As part of STOP, AHIP released the STOP Measure, which allows plans to compare physician prescribing practices to the Centers for Disease Control ("CDC") Guideline for Prescribing Opioids for Chronic Pain. [51]

The CDC Guideline was released in March 2016, after a notice and comment process, to help physicians decide whether to prescribe opioids and to provide advice on "medication selection, dosage, duration and discontinuation of treatment."[52] An article in JAMA Internal Medicine reviewed the comments submitted on the Guideline and found that, among the 150 organizations that submitted comments, opposition to the Guideline was associated with having received funding from opioid manufacturers, as was opposition specifically to the recommendations about dosing and duration of treatment.[53]

The Senate's Homeland Security and Governmental Affairs Committee opened an investigation in Mar. 2017 into the makers of the five opioid medications with the highest sales.[54] The investigation sought to determine "whether pharmaceutical manufacturers—at the head of the opioids pipeline—have contributed to opioid over-utilization and over-prescription . . . ." [55] Senator Claire McCaskill, in her letter to the manufacturers, who did not include Mallinckrodt, opined that the opioid epidemic "is the direct result of a calculated sales and marketing strategy major opioid manufacturers have allegedly pursued over the past 20 years to expand their market share and increase dependency on powerful — and often deadly — painkillers."[56] Specifically, she wrote, manufacturers "downplay[ed] the risk of addition"

In sum, the opioid abuse crisis is one of the most urgent social problems facing the U.S., with major effects on health, prosperity and well-being. Significant attention and criticism have focused on opioid manufacturers for deceptively promoting opioids, inappropriately intervening the legislative and political process and influencing physician prescribing, both directly and indirectly, through trade associations and other groups. Accordingly, the subject of the Proposal—how Mallinckrodt has changed its corporate

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[48] https://www.mdedge.com/ccjm/article/109138/drug-therapy/fifth-vital-sign-complex-story-politics-and-patient-care

[49] http://myfloridalegal.com/webfiles.nsf/WF/JMAR-ARCKCD/$file/NAAG-Opioid-Letter-to-AHIP.pdf

[50] https://www.ahip.org/health-plans-launch-new-stop-initiative-to-help-battle-opioid-crisis-in-america/

[51] https://www.ahip.org/health-plans-launch-new-stop-initiative-to-help-battle-opioid-crisis-in-america/

[52] https://www.cdc.gov/media/releases/2016/p0315-prescribing-opioids-guidelines.html

[53] https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2598092?redirect=true

[54] Dan Mangan, "Opioid Epidemic: Senate Committee Opens Probe of Five Big Painkiller Makers," CNBC, Mar. 28, 2017 (https://www.cnbc.com/2017/03/28/senate-committee-opens-probe-of-five-big-opioid-makers.html); https://www.motherjones.com/politics/2017/03/opioid-investigation-mccaskill-pharmaceutical-companies/

[55] Dan Mangan, "Opioid Epidemic: Senate Committee Opens Probe of Five Big Painkiller Makers," CNBC, Mar. 28, 2017 (https://www.cnbc.com/2017/03/28/senate-committee-opens-probe-of-five-big-opioid-makers.html)

[56] Dan Mangan, "Opioid Epidemic: Senate Committee Opens Probe of Five Big Painkiller Makers," CNBC, Mar. 28, 2017 (https://www.cnbc.com/2017/03/28/senate-committee-opens-probe-of-five-big-opioid-makers.html)

governance to monitor and manage opioid-related risks—is a significant social policy issue with a strong connection to Mallinckrodt.

The "Sale of Products" Determinations Do Not Apply Because the Proposal Deals with a Significant Social Policy Issue

Mallinckrodt rests its argument on previous determinations in which the Staff permitted companies that sold or distributed products to exclude proposals related to those products on ordinary business grounds. The proposals in those determinations, which fall into three categories, differ from the Proposal in important ways. Mallinckrodt also neglected to mention a recent determination declining to allow exclusion on ordinary business grounds of a proposal nearly identical to the Proposal submitted at a pharmaceutical distributor.

First, Mallinckrodt points to proposals submitted last year to AbbVie[57] and Johnson & Johnson,[58] which asked those companies to report on their policies for safe disposal of prescription drugs to prevent water pollution and possible options to address that problem, including the endorsement or funding of industry take-back programs. Both AbbVie and Johnson & Johnson argued, among other things, that the proposals dealt with their ordinary business operations, urging that they addressed customer disposal and misuse of their products. The Staff concurred with the companies' positions, stating simply that the proposals related to the companies' ordinary business operations.

The Staff thus implicitly rejected the proponents' claims that the proposals dealt with a significant social policy issue. In opposing the Johnson & Johnson no-action request, the proponent had argued that the proposals addressed "the significant public policy issue of reducing water pollution caused by disposal of used pharmaceuticals." In responding to both requests, the proponents had attempted to tie the take-back issue to the larger problem of the opioid crisis.

The AbbVie and Johnson & Johnson determinations are not dispositive here, however, because the connection to the opioid crisis was more remote in those proposals. Both proposals' supporting statements addressed concerns over water pollution in addition to the possibility of poisoning or opioid misuse resulting from the lack of safe disposal options for leftover opioid medications. The public debate described in the Johnson & Johnson no-action response related almost entirely to take-back programs.

The AbbVie and Johnson & Johnson proposals' supporting statements also discussed the mechanics and funding of take-back programs for prescription drugs and other hazardous products. In that way, the AbbVie and Johnson & Johnson proposals were much more operationally focused than the Proposal, which confines its scope to governance measures aimed at better managing opioid-related risks. Unlike the proposals in AbbVie and Johnson & Johnson, the Proposal does not concern itself with specific product-related practices.

The second group of determinations on which Mallinckrodt relies involve proposals submitted to distributors or retailers, but not manufacturers, addressing risks related to the sale or distribution of controversial products such as tobacco, firearms and products tested on animals, which were deemed excludable on ordinary business grounds.[59] Although the reasoning for those determinations is not provided, it is possible to infer that the Staff believed that the proposal subjects did not qualify as significant

[57] AbbVie Inc. (Mar. 16, 2017)

[58] Johnson & Johnson (Jan. 30, 2017)

[59] See determinations cited on pages 4-6 of the No-Action Request.

social policy issues or that a sufficient nexus did not exist between the companies, whose involvement with the products was essentially passive, and the policy issues associated with the products themselves.

Mallinckrodt also cites two determinations allowing omission of proposals at drug manufacturers Pfizer[60] (drugs used in executions) and Eli Lilly[61] (price increases on specific drugs). As with the proposals described above, it appears likely that the Staff did not view the issues raised by the proposals as significant social policy issues, given that the nexus between the companies and issues was strong.

The Staff's recent determination in AmerisourceBergen Corporation,[62] on a proposal nearly identical to the Proposal, supports our contention that the opioid crisis is a significant social policy issue and was not mentioned by Mallinckrodt. In that determination, the Staff rejected a drug distributor's argument that the required nexus between the opioid crisis and the company's activities as a distributor did not exist. If the nexus is strong enough for a distributor, manufacturers, who are blamed equally, if not more, for opioid misuse, must have a sufficiently strong nexus.

Mallinckrodt's protestation that "[o]pioid products account for only a small portion—less than 10%--of Mallinckrodt's total revenues" does not undermine the strength of the nexus. Companies sometimes use a "rule of thumb" that a misstatement or omission is material if it involves 5% or more of revenues, though the Staff has indicated that solely using a numeric threshold is inappropriate.[63] As well, under the recent Staff Legal Bulletin 14I,[64] an argument like this one about nexus should be part of a submission reflecting the board's consideration of the Proposal's subject in the context of the company's business. The absence of such a submission substantially weakens Mallinckrodt's argument.

The Proposal's Subject is Not Mallinckrodt's Compliance Program

Mallinckrodt also contends that the Proposal's topic is the Company's compliance program, citing determinations that have permitted omission on ordinary business grounds of proposals addressing legal compliance. That claim is inconsistent with the actual language of the Proposal and ignores the fact that the Proposal deals with a significant social policy issue.

Unlike the numerous determinations discussed on page six of the No-Action Request, the Proposal does not ask for reporting on how Mallinckrodt is ensuring compliance with a specific law or adoption of a new policy aimed at improving compliance. Potential liability stemming from culpability in the opioid crisis forms the backdrop for the Proposal, but is not the Proposal's primary thrust. Instead, the Proposal focuses on governance measures to manage risk going forward.

It is worth noting that even a proposal focused more directly on compliance is not excludable if the subject qualifies as a significant social policy issue. For example, the Commission has stated that "significant employment discrimination matters," which by their nature involve legal compliance, are a significant social policy issue.[65] Here, given that the opioid crisis is a significant social policy issue, the remote connection between the Proposal and legal compliance does not support exclusion.

The Proposal Would Not Micromanage Mallinckrodt

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[60] Pfizer Inc. (Mar. 1, 2016)
[61] Eli Lilly and Company (Feb. 10, 2017)
[62] AmerisourceBergen Corporation (Jan. 11, 2018)
[63] Staff Accounting Bulletin No. 99, "Materiality" (Aug. 12, 1999)
[64] Staff Legal Bulletin 14I (Nov. 1, 2017)
[65] Exchange Act Release No. 40018 (May 21, 1998)

The Commission has articulated the two "central considerations" animating the ordinary business exclusion:

1. "Certain tasks are so fundamental to management's ability to run a company on a day-to-day basis that they could not, as a practical matter, be subject to direct shareholder oversight"; and

2. "the degree to which the proposal seeks to 'micro-manage' the company by probing too deeply into matters of a complex nature upon which shareholders, as a group, would not be in a position to make an informed judgment."[66]

Mallinckrodt urges that the Proposal would micromanage it because it seeks to control "decisions regarding the manufacture and sale of particular products, compliance with laws and regulations and its allocation of capital resources."[67]

Unlike the proposals in many of the determinations cited by Mallinckrodt, the Proposal does not seek to control which products Mallinckrodt distributes, but rather asks for a single report to shareholders. We acknowledge that allowing shareholders to make day-to-day decisions about product selection would be impractical and undesirable. Nor does the Proposal ask for detailed reporting or operational changes related to a technical subject, as the proposals in Ford Motor Co.[68] and Marriott International[69] did.

Mallinckrodt also urges that the Proposal would require disclosure of complex information that would be difficult for shareholders to understand. There is no support in the Proposal for Mallinckrodt's claim that it seeks disclosure about "the decisions necessary to manage its ordinary business of producing and selling opioid-containing products while attempting to minimize harm associated with potential diversion and misuse of such products."[70]

The kinds of governance measures discussed in the Proposal—board oversight of risk, compensation metrics, stakeholder engagement and political activity policies—are the subject of shareholder proposals on which shareholders frequently cast votes, and companies themselves often make significant amounts of disclosure on these governance arrangements. The Proposal does not even urge the adoption of any particular governance measure, but only asks for reporting on what Mallinckrodt has already done. Accordingly, the Proposal cannot be said to micromanage Mallinckrodt.

Substantial Implementation

Mallinckrodt contends it has substantially implemented the Proposal through its existing disclosures. First, Mallinckrodt points to its website disclosure regarding anti-diversion efforts and disclosure in its annual report regarding compliance and anti-diversion programs. None of those disclosures is responsive to the Proposal, which focuses on governance rather than operational measures.

Mallinckrodt also argues that it has substantially implemented the Proposal's request for disclosure of board oversight of opioid-related risks. Mallinckrodt asserts that the Company's 2017 proxy statement "describes the committees of the Board and their and management's roles in regularly reviewing and monitoring key risks, including financial and reputational risks related to the sale of opioid-containing

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[66] Exchange Act Release No. 40018 (May 21, 1998)

[67] No-Action Request, at 11

[68] Ford Motor Company (Mar. 2, 2004)

[69] Marriott International Inc. (Mar. 17, 2010)

[70] No-Action Request, at 12

products."[71] But the terms "opioid" and "controlled substance" do not appear in the Company's proxy statement. The No-Action Request refers obliquely to Mallinckrodt's Corporate Governance Guidelines and board committee charters, but the Corporate Governance Guidelines, Compliance Committee Charter and Audit Committee Charter are all silent on both opioids and controlled substances.

Mallinckrodt would apparently like shareholders to infer that references to risk and compliance in the Company's governance documents encompass opioid-related matters. There is no reason for shareholders to make those assumptions, though. The purpose of the Proposal is to obtain information about governance measures that Mallinckrodt affirmatively states are intended to help the Company more effectively manage opioid-related risks. Disclosures that refer generically to risk or compliance do not provide the requested information. If indeed opioid-related risks are simply lumped in with other risks, with no special governance mechanisms or considerations, then Mallinckrodt could substantially implement the Proposal by saying so. Its current disclosures, however, fall far short.

* * *

For the reasons set forth above, Mallinckrodt has not met its burden of showing that it is entitled to omit the Proposal in reliance on Rule 14a-8(i)(7) or Rule 14a-8(i)(10). The Proponents thus respectfully request that Mallinckrodt's request for relief be denied.

The Proponents appreciate the opportunity to be of assistance in this matter. If you have any questions or need additional information, please contact me at (513) 673-9992 or Donna Meyer, Director of Shareholder Advocacy, (713) 299-5018, dmeyer@mercyinvestments.org.

Sincerely,

Susan S. Makos

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[71] No-Action Request, at 14

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January 12, 2018

VIA EMAIL (SHAREHOLDERPROPOSALS@SEC.GOV)

Office of Chief Counsel
Division of Corporation Finance
U.S. Securities and Exchange Commission
100 F Street, N.E.
Washington, D.C. 20549

Re: *Shareholder Proposal to Mallinckrodt plc by Mercy Investment Services, Inc., Providence Trust and Catholic Health Initiatives*

Ladies and Gentlemen:

Pursuant to Rule 14a-8(j) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), we are writing on behalf of our client, Mallinckrodt plc, an Irish public limited company ("Mallinckrodt" or the "Company"), to request that the Staff of the Division of Corporation Finance (the "Staff") of the U.S. Securities and Exchange Commission (the "Commission") concur with Mallinckrodt's view that, for the reasons stated below, it may exclude the shareholder proposal (the "Proposal") and the statement in support thereof (the "Supporting Statement") received from Mercy Investment Services, Inc., Providence

Trust, and Catholic Health Initiatives (collectively, the "Proponents") from Mallinckrodt's proxy statement and form of proxy for its 2018 Annual General Meeting of Shareholders (collectively, the "2018 Proxy Materials").

Pursuant to Rule 14a-8(j) under the Exchange Act, we have:

- transmitted this letter by email to the Staff at shareholderproposals@sec.gov no later than eighty (80) calendar days before the Company intends to file its definitive 2018 Proxy Materials with the Commission, which is currently anticipated to be on or about April 6, 2018; and

- concurrently sent copies of this letter, together with its attachments, to the Proponents at the email addresses they have provided as notice of the Company's intent to exclude the Proposal and the Supporting Statement from the 2018 Proxy Materials.

Rule 14a-8(k) and Staff Legal Bulletin No. 14D (Nov. 7, 2008) ("SLB 14D") provide that stockholder proponents are required to send companies a copy of any correspondence that the proponents elect to submit to the Commission or the Staff. Accordingly, we are taking this opportunity to inform the Proponents that if the Proponents elect to submit additional correspondence to the Commission or the Staff with respect to the Proposal, a copy of that correspondence should be furnished concurrently to the undersigned on behalf of the Company pursuant to Rule 14a-8(k) and SLB 14D.

THE PROPOSAL

The Proposal, dated September 15, 2017 (in the case of the letter from Mercy Investment Services, Inc. and Providence Trust) and September 19, 2017 (in the case of the letter from Catholic Health Initiatives), sets forth the following proposed resolution for the vote of the Company's stockholders at the Annual General Meeting of Shareholders in 2018:

> RESOLVED, that shareholders of Mallinckrodt plc ("Mallinckrodt") urge the Board of Directors (the "Board") to report to shareholders by September 30, 2018 on the governance measures Mallinckrodt has implemented since 2012 to more effectively monitor and manage financial and reputational risks related to the opioid crisis in the U.S., given Mallinckrodt's sale of opioid medications and active pharmaceutical ingredients in opioid medications, including whether Mallinckrodt has assigned responsibility for such monitoring to the Board or one or more Board committees, revised senior executive compensation metrics or policies, adopted or changed mechanisms for obtaining input from stakeholders, or altered policies or processes regarding company political activities.

The report should be prepared at reasonable cost and should omit confidential and proprietary information.

Copies of the Proposal and the Supporting Statement are attached to this letter as Exhibit A.

BASES FOR EXCLUSION

The Company respectfully requests that the Staff concur in its view that the Proposal and the Supporting Statement may be excluded from the 2018 Proxy Materials pursuant to (i) Rule 14a-8(i)(7), because the Proposal involves matters that relate to the ordinary business operations of the Company and/or (ii) Rule 14a-8(i)(10), because the Company has already substantially implemented the Proposal.

ANALYSIS

I. The Company May Exclude the Proposal Pursuant to Rule 14a-8(i)(7) Because the Proposal Involves Matters that Relate to Mallinckrodt's Ordinary Business Operations.

A. Rule 14a-8(i)(7) and the Ordinary Business Exclusion.

Rule 14a-8(i)(7) permits a company to exclude a stockholder proposal from its proxy materials "[i]f the proposal deals with a matter relating to the company's ordinary business operations." The "general underlying policy" of the ordinary business exclusion is "to confine the resolution of ordinary business problems to management and the board of directors, since it is impracticable for shareholders to decide how to solve such problems at an annual shareholders meeting." Exchange Act Release No. 34-418 (May 21, 1998) (the "1998 Release"). The Commission has identified two central considerations that underlie this policy: First, that "[c]ertain tasks are so fundamental to management's ability to run a company on a day-to-day basis that they could not, as a practical matter, be subject to direct shareholder oversight," and second, "the degree to which the proposal seeks to 'micro-manage' the company by probing too deeply into matters of a complex nature upon which stockholders, as a group, would not be in a position to make an informed judgment." Id. (citing Exchange Act Release No. 12999 (Nov. 22, 1976)).

B. Whether Proposals Requesting Reports Relate to Ordinary Business Depends on the Underlying Subject Matter of the Proposed Report.

With respect to proposals requesting the preparation and dissemination of a report regarding one or more aspects of a company's business, the Commission has stated that the Staff "will consider whether the subject matter of the special report . . . involves a matter of ordinary

business; where it does, the proposal will be excludable" under Rule 14a-8(i)(7). Exchange Act Release No. 34-20091 (Aug. 16, 1983). Similarly, where a proposal relates to an evaluation of risk, "rather than focusing on whether a proposal and supporting statement relate to the company engaging in an evaluation of risk, [the Staff] will instead focus on the subject matter to which the risk pertains or that gives rise to the risk." Staff Legal Bulletin 14E (Oct. 27, 2009) ("SLB 14E").

C. The Subject Matter of the Proposal Fundamentally Involves Matters of Ordinary Business.

i. The core subject matter of the proposal is the manufacture and sale of products, which are at the heart of the Company's ordinary business.

The Staff has consistently taken the position that shareholder proposals relating to the sale of particular products are excludable because they relate to ordinary business operations. The Proposal requests a report on "measures Mallinckrodt has implemented since 2012 to more effectively monitor and manage financial and reputational risks related to the opioid crisis in the U.S., given Mallinckrodt's sale of opioid medications and active pharmaceutical ingredients." The measures that Mallinckrodt has taken, which are summarized in Section C below, are fundamentally ordinary business matters and the Proposal is therefore excludable on this basis.

As set forth in SLB 14E, the Staff will "look to the underlying subject matter of the report . . . to determine whether the proposal relates to ordinary business." The Staff has routinely found that decisions regarding the selection of products for sale and the manner of manufacturing and selling products are core aspects of companies' ordinary business activities.

For example, the Staff recently granted no-action relief to Abbvie and Johnson & Johnson when each of them sought to exclude a shareholder proposal requesting that the company's board of directors prepare and publish a report reviewing the company's existing policies for safe disposition by users of prescription drugs to prevent misuse (and thereby prevent water pollution), and setting forth policy options for a proactive response, including determining whether the company should endorse partial or full industry responsibility for take-back programs by providing funding or resources for such programs. AbbVie Inc. (Mar. 16, 2017) and Johnson & Johnson (Jan. 30, 2017). See also Cardinal Health, Inc. (Aug. 4, 2017) (concurring in the exclusion of a proposal requesting that the company issue a report describing the controlled distribution systems it implements to prevent the diversion of restricted medicines to prisons for use in executions, and its process for monitoring and auditing these systems, noting that the proposal related "to the sale or distribution of particular products to its customers"); McKesson Corp. (Jun. 1, 2017) (same); Pfizer Inc. (Mar. 1, 2016) (granting relief to exclude a proposal describing the steps the company has taken or will take to identify and remedy the flaws in its current distribution system for medicines listed in the formal execution protocols of certain

U.S. states in order to prevent their sale to prisons for the purpose of aiding executions); Rite Aid Corporation (Mar. 24, 2015) (granting relief regarding a proposal requesting additional board committee oversight concerning the sale of certain products, in particular, tobacco products, and noting that "[p]roposals concerning the sale of particular products and services are generally excludable under rule 14a-8(i)(7)"); and Wal-Mart Stores, Inc. (Mar. 20, 2014) (granting relief regarding a proposal requesting additional board committee oversight concerning the sale of certain products, in particular, firearms).

Similarly, in Walgreens Boots Alliance, Inc. (Nov. 7, 2016, recon. denied Nov. 22, 2016), the Staff concurred with the exclusion of a proposal requesting that the board issue a report "assessing the financial risk, including long-term legal and reputational risk, of continued sales of tobacco products in the company's stores" because the proposal related to the company's ordinary business operations of selling products. Like the proposal in Walgreens, which focused on the financial and reputational risks of tobacco products, the Proposal focuses on "financial and reputational risks related to the opioid crisis," which are a subset of the risks related to the Company's sale of products containing opioids. Decisions regarding the management of these risks are not suitable for direct shareholder oversight and are "fundamental to management's ability to run a company on a day-to-day basis" as described in the 1998 Release. See also Wells Fargo & Co. (Jan. 28, 2013, recon. denied Mar. 4, 2013) (concurring in the exclusion of a proposal requesting that the board prepare a report discussing the adequacy of the company's policies in addressing the social and financial impacts of direct deposit advance lending because the proposal related to the products and services offered for sale by the company); Amazon.com, Inc. (Mar. 11, 2016) (concurring in the exclusion of a proposal requesting that Amazon issue a report addressing animal cruelty in its supply chain, including assessing "the reputational and financial risks associated with lack of a consistent prohibition on products involving animal cruelty," because the proposal related "to the products and services offered for sale by the company"); Eli Lilly and Company (Feb. 10, 2017) (concurring in the exclusion of a proposal requesting that the board issue a report including, among other things, an assessment of the legislative, regulatory, reputational and financial risks related to the rates of price increases of the company's top ten branded prescription drugs by sales); and AT&T Inc. (Feb. 13, 2012) (concurring in the exclusion of a proposal requesting a report on financial and reputational risks posed by continuing to use technology that inefficiently consumed electricity).

The Proposal seeks a vote on whether Mallinckrodt should prepare a report regarding risks associated with its manufacture and sale of particular products—those containing opioids. Decisions regarding the manner in which the Company manufactures and sells its products, and the selection of the products it sells and management of the associated risks, are critical day-to-day activities of the Company's management and subject to direct oversight by the Board, as reviewed in more detail below. Control over decisions regarding the manufacture and sale of opioids and managing the risks associated therewith are fundamental to

management's ability to run the Company on a day-to-day basis and are not well-suited to direct shareholder oversight.

ii. The subject matter of the proposal involves the Company's compliance with laws and regulations and its efforts to prevent misuse of its products by customers, which are also part of its ordinary business operations.

To the extent that the report requested by the Proposal is intended to review the Company's compliance with existing laws and regulations regarding opioids in particular or controlled substances more generally, this too is an ordinary business matter of the Company that is not well-suited to direct oversight by shareholders. In a long line of no-action letters, the Staff has consistently agreed that proposals relating to compliance with laws and regulations, including in particular several proposals requesting the preparation and dissemination of a report regarding such compliance and/or risk management more generally, involve ordinary business matters and are excludable under Rule 14a-8(i)(7). See, e.g., Navient Corp. (Mar. 26, 2015) (concurring in the exclusion of a proposal requesting a report on the company's internal controls over its student loan servicing operations, including a discussion of the actions taken to ensure compliance with applicable federal and state laws, as "concern[ing the] company's legal compliance program"); Raytheon Co. (Mar. 25, 2013) (concurring in the exclusion of a proposal requesting a report on the board's oversight of the company's efforts to implement the provisions of the Americans with Disabilities Act, the Fair Labor Standards Act, and the Age Discrimination in Employment Act because "[p]roposals that concern a company's legal compliance program are generally excludable under rule 14a-8(i)(7)"); FMC Corp. (Feb. 25, 2011, recon. denied Mar. 16, 2011) (concurring in the exclusion of a proposal requesting that the board establish a product stewardship program by, among other things, preparing a "report . . . addressing all documented [pesticide] product misuses worldwide . . . and proposing changes to prevent further misuse"); FedEx Corp. (July 14, 2009) (concurring in the exclusion of a proposal requesting a report discussing the compliance of the company and its contractors with state and federal laws governing proper classification of employees and independent contractors); Verizon Communications Inc. (Jan. 7, 2008) (concurring in the exclusion of a proposal requesting the board adopt policies to ensure the company and its contractors do not engage in illegal trespass actions and prepare a report to shareholders describing the company's policies for preventing and handling illegal trespassing incidents); and Halliburton Co. (Mar. 10, 2006) (concurring in the exclusion of a proposal requesting a report evaluating the potential impact of certain violations and investigations on the company's reputation and stock price, as well as the company's plan to prevent further violations, "as relating to [the company's] ordinary business operations (i.e., general conduct of a legal compliance program)").

As a long-time manufacturer of controlled substances, Mallinckrodt, its management and its Board are intimately involved in legal and regulatory compliance activities generally and seek strict compliance with controlled substance laws and regulations in particular.

Mallinckrodt has undertaken robust efforts to prevent misuse of its products as a matter of its day-to-day business activities relating to the manufacture and sale of its opioid-containing products, as discussed in more detail below. The manner in which the Company monitors and enforces its compliance with various laws and regulations, and attempts to prevent misuse of its products by end-users, are ordinary business matters handled directly by management and overseen by the Compliance Committee of the Board in particular and the full Board more generally. The manner in which the Company monitors such compliance, and the decisions it makes in managing the risks associated therewith, are "matters of a complex nature upon which shareholders, as a group, would not be in a position to make an informed judgment." The 1998 Release.

D. Although Opioid Abuse Is a Serious Issue, the Proposal Does Not Raise a Significant Social Policy Issue that Transcends the Company's Ordinary Business.

The sole exception to the general rule permitting exclusion on ordinary-course grounds of matters that are fundamental to management's ability to run a company on a day-to-day basis as outlined above is for "proposals relating to such matters but focusing on sufficiently significant social policy issues (e.g., significant discrimination matters)" that "transcend the day-to-day business matters and raise policy issues so significant that it would be appropriate for a shareholder vote." The 1998 Release. As discussed below, the Board acknowledges that opioid abuse is a tragic national crisis that demands and deserves a comprehensive policy response. But the fact that a shareholder proposal touches on admittedly important policy issue in and of itself does not render the proposal non-excludable on ordinary-course grounds. See, e.g., PetSmart, Inc. (Mar. 24, 2011) (concurring with the exclusion of a proposal requesting that the board require its suppliers to certify that they had not violated "the Animal Welfare Act, the Lacey Act, or any state law equivalents," even though the Staff acknowledged that "the humane treatment of animals is a significant policy issue," because the scope of the proposal was overly broad and related to a variety of ordinary business matters); and General Electric Co. (Feb. 3, 2005) (concurring in the exclusion of a proposal relating to, among other things, the elimination of jobs within GE and/or relocation of U.S.-based jobs to foreign countries, which the Staff had indicated was a significant policy issue, because the proposal also touched upon job losses within the entire company, whether or not related to the overseas relocation of jobs, and thus dealt with ordinary business matters, "i.e., management of the workforce"). See also Rite Aid Corporation (Mar. 24, 2015) (excluded proposal involving sales of tobacco products); Wal-Mart Stores, Inc. (Mar. 20, 2014) (excluded proposal involving sales of firearms with high-capacity magazines); Cardinal Health, Inc. (Aug. 4, 2017) (excluded proposal involving report on diversion of medicines to prisons for executions); McKesson Corp. (Jun. 1, 2017) (same); Pfizer Inc. (Mar. 1, 2017) (excluded proposal involving report on sale of medicines to prisons for executions); and The Walt Disney Company and Comcast Corporation, infra (excluded proposals involving reports on political spending and lobbying). After thorough review and consideration, the Board

does not believe that the Proposal transcends the day-to-day business operations of the Company.[1]

i. The underlying subject matter of the proposal involves ordinary business matters.

The Proposal requests that the Board to report on "measures Mallinckrodt has implemented since 2012 to more effectively monitor and manage financial and reputational risks related to the opioid crisis in the U.S., given Mallinckrodt's sale of opioid medications and active pharmaceutical ingredients in opioid medications." The effective monitoring and management of financial and reputational risks (including with respect to compliance with laws and regulations regarding controlled substances and preventing misuse by end-users of the Company's products) do not "transcend" Mallinckrodt's ordinary business. Indeed, making and selling pharmaceutical products, such as opioids, and making the complex judgments associated with managing risks associated with operating its businesses, including ensuring compliance with laws and regulations, are the ordinary business of management, overseen by the Board and its committees.

This Proposal is similar to other proposals that sought to avoid exclusion under Rule 14a-8(i)(7) by attempting to connect a shareholder proposal that was fundamentally about ordinary business matters to an obviously significant policy issue. Very recently, for example, the Staff recognized that although a proposal by shareholders of The Walt Disney Company referred to the company's political spending and lobbying (which spending the Staff has previously viewed as a significant policy issue), the thrust of the proposal was the content and management of the company's news programming, decisions about which are the company's ordinary business. The Walt Disney Company (Dec. 12, 2017). Similarly**,** another recent shareholder proposal sought a board report on Comcast's assessment of the political activity and lobbying resulting from its media outlet and its exposure to risks resulting therefrom. Comcast Corporation (Mar. 2, 2017). The proposal sought to characterize Comcast's spending of funds used to operate its media outlet as political spending and lobbying. However, the crux of the proposal was the company's operation of its media outlet, an ordinary business matter for

[1] On November 1, 2017, the Staff published Staff Legal Bulletin No. 14I, which announced a new Staff policy regarding the application of Rule 14a-8(i)(7). The Staff stated that the applicability of the significant policy exception "depends, in part, on the connection between the significant policy issue and the company's business operations," which may involve a "difficult judgment call," but that the company's board of directors "is well situated to analyze, determine and explain whether a particular issue is sufficiently significant because the matter transcends ordinary business and would be appropriate for a shareholder vote." The Nominating and Governance Committee (the "Governance Committee") of the Board reviewed the Proposal and Supporting Statement in consultation with management, and the discussion herein reflects the review and analyses of the Governance Committee, which was subsequently approved by the full Board, as well as the Company's management.

Comcast. See also Rite Aid Corporation; Wal-Mart Stores, Inc.; Cardinal Health, Inc.; McKesson Corp.; and Pfizer Inc., supra.

As such, the fact that the Proposal relates to the opioid crisis, which itself involves a significant policy issue, does not preclude the Proposal from exclusion under Rule 14a-8(i)(7). See, e.g., Apache Corporation, (March 5, 2008) (proposal seeking the implementation of certain equal employment opportunity principles prohibiting discrimination based on sexual orientation and gender identity excludable where "some of the principles relate[d] to Apache's ordinary business operations"). As detailed above, the underlying thrust of the Proposal is the Company's manufacture and sale of particular products in the ordinary course of its business and its compliance with laws in connection with such operations, which are squarely ordinary business matters and do not "transcend" Mallinckrodt's day-to-day operations.

ii. There is not a sufficient nexus between the nature of the Proposal—which seeks to reduce opioid abuse—and the Company.

The Staff further elaborated on the significant social policy exception in SLB 14E, stating that "[i]n those cases in which a proposal's underlying subject matter transcends the day-to-day business matters of the company and raises policy issues so significant that it would be appropriate for a shareholder vote, the proposal generally will not be excludable under Rule 14a-8(i)(7) as long as a sufficient nexus exists between the nature of the proposal and the company" (emphasis added). The Staff also stated that "[c]onversely, in those cases in which a proposal's underlying subject matter involves an ordinary business matter to the company, the proposal generally will be excludable under Rule 14a-8(i)(7)" (emphasis added).

There is not a sufficient nexus between the policy issues implicated by the Proposal—which, as indicated in the Supporting Statement, ultimately aims to reduce opioid abuse and misuse—on the one hand, and Mallinckrodt's ordinary business of manufacturing and selling opioid-containing products, on the other hand, for two reasons: First, Mallinckrodt is a manufacturer of controlled substances, including opioids, but does not promote or distribute controlled substances directly to physicians, patients, or any other end-user and, second, opioid products constitute only a small portion of Mallinckrodt's revenues.

(A) Mallinckrodt does not market or promote its opioid products directly to physicians or patients.

Mallinckrodt does not market or promote its opioid products to physicians or patients and does not prescribe its opioid products to patients. The Supporting Statement misleadingly attempts to present Mallinckrodt as having a starring role in the abuse and misuse of opioids by stating, among other things, that "Mallinckrodt accounted for 43.8 million of the 236 million opioid prescriptions filled in 2016, according to IMS Health," without mentioning

that Mallinckrodt itself filled zero such prescriptions—all such prescriptions were given by healthcare providers and filled by pharmacists, who in turn were generally supplied by third-party distributors. More than 90% of Mallinckrodt's solid dose generic and non-promoted branded opioids are sold to distributors and large centralized distribution centers, who then in turn supply individual retail pharmacies to fill patient prescriptions. Mallinckrodt has robust legal and regulatory compliance programs and takes the opioid crisis very seriously. Nevertheless, it has only an attenuated role in the risks of abuse of opioids by end-users because it does not interact with end-users in the course of its ordinary business operations. The underlying policy concerns of the Proponents—reducing and ultimately solving opioid abuse—must be primarily addressed by parties closer to the ultimate end-users than Mallinckrodt, and a report regarding measures taken to mitigate such risks would itself demonstrate a limited nexus between the Company and the real and ongoing dangers of the opioid crisis.

The Supporting Statement draws attention to the dire consequences of the opioid crisis by, for example, citing data from the Centers for Disease Control and Prevention (the "CDC") on the high number of recent deaths in the United States from opioid abuse. But the Supporting Statement does not mention that research detailed on the CDC's website has identified the following specific risk factors that make people particularly vulnerable to prescription opioid abuse and overdose: "[o]btaining overlapping prescriptions from multiple providers and pharmacies . . .[t]aking high daily dosages of prescription pain relievers . . . [h]aving mental illness or a history of alcohol or other substance abuse . . .and "[l]iving in rural areas and having low income."[2] None of these risk factors relate to the Company's ordinary business of manufacturing pharmaceutical products and selling them to third-party distributors.

According to the CDC's assessment, to prevent opioid overdose deaths, primary care clinicians and physicians must follow proper prescription practices: "[t]o reverse this epidemic, we need to improve the way we treat pain. We must prevent abuse, addiction, and overdose before they start."[3] The CDC's recommendations focus on assisting physicians to determine when to initiate or continue opioids for chronic pain. The guidelines discuss several effective alternatives for treating chronic pain, suggesting that patients have been prescribed opioids despite the availability of other alternatives. None of these matters relate directly to the Company and are not suitable topics for reports by the Company or proper subjects for votes of the Company's shareholders because they are simply not sufficiently connected to the Company's ordinary business or governance.

[2] https://www.cdc.gov/drugoverdose/opioids/prescribed.html#tabs-2-2.
[3] Id.

(B) Opioid-containing products constitute only a small portion of Mallinckrodt's revenues.

Mallinckrodt is a global specialty pharmaceutical company that offers a wide range of products. Opioid products account for only a small portion—less than 10%—of Mallinckrodt's total revenues. During that period, Mallinckrodt's Specialty Generics business segment accounted for roughly one-third (1/3) of the Company's overall annual revenue and approximately half of the revenue in that business segment comes from sales of active pharmaceutical ingredients to other manufacturers. Revenues derived from production and sales of "solid dose" medicines (*i.e.*, pills) make up the other half of segment revenues.

E. The Proposal Seeks to Micromanage the Company.

The Staff has consistently granted relief under Rule 14a-8(i)(7) for proposals that seek to "micromanage the company by probing too deeply into matters of a complex nature upon which shareholders, as a group, would not be in a position to make an informed judgment." See, e.g., The Wendy's Company (Mar. 2, 2017) (granting relief for a proposal urging the board "to take all necessary steps to join the Fair Food Program as promptly as feasible for the purpose of protecting and enhancing consumer and investor confidence in the Wendy's brand as it relates to the purchase of produce, and to prepare a report concerning the implementation of the proposal"). By seeking a report regarding risk management of fundamentally ordinary business matters, the Proposal seeks to micromanage the Company's business, and in particular its decisions regarding the manufacture and sale of particular products, compliance with laws and regulations and its allocation of capital resources. The Staff has consistently concurred with requests to exclude such proposals. See, e.g., Apple Inc. (Dec. 5, 2016) (proposal requesting that the board generate a feasible plan to reach net-zero GHG emission status by 2030 for business aspects directly owned by the company and major suppliers and report the plan to shareholders was excludable for micro-managing despite the company's recognition that climate change is a significant policy issue); Deere & Company (Dec. 5, 2016) (same proposal as Apple, supra, and excluded on the same basis); Marriott International Inc. (March 17, 2010) (proposal to limit showerhead flow to no more than 1.6 gallons per minute and requiring the installation of mechanical switches to control the level of water flow was excludable for micromanaging despite the Staff's recognition that global warming, which the proposal sought to address, is a significant policy issue); and Ford Motor Company (March 2, 2004) (proposal requesting the preparation and publication of a scientific report regarding the existence of global warming or cooling was excludable "as relating to ordinary business operations").

Overseeing compliance with laws and regulations related to specific products and managing risks relating thereto are the types of day-to-day business operating decisions and responsibilities that the Commission stated in the 1998 Release are too impractical and complex to be subject to direct shareholder oversight. The opioid crisis presents a host of interlocking and

extremely complex issues that are not easily solved by any one actor or group of actors in the healthcare system. The Company's various potential and actual responses to the risks of opioid abuse by end-users, and the decisions necessary to manage its ordinary business of producing and selling opioid-containing products while attempting to minimize harm associated with potential diversion and misuse of such products are inherently too complex for shareholder votes at annual meetings. The report sought by the Proposal, even if prepared, would not be sufficient for shareholders to make informed decisions about the Company's ordinary business decisions regarding the production and sale of opioid-containing products. As described in the 1998 Release, it would be "impracticable for shareholders to decide how to solve such problems at an annual shareholders meeting."

II. The Company May Exclude the Proposal Pursuant to Rule 14a-8(i)(10) Because the Company has Already Substantially Implemented the Proposal.

Rule 14a-8(i)(10) provides that a company may exclude a stockholder proposal from its proxy materials "[i]f the company has already substantially implemented the proposal." In its adopting release, the Commission explained that the Rule was "designed to avoid the possibility of shareholders having to consider matters which have already been favorably acted upon by the management . . ." Exchange Act Release No. 12,598, 9 SEC Dock. 1030, 1035 (1976). In determining whether a proposal has been "substantially implemented," the Staff has held that the determination "depends upon whether [the company's] particular policies, practices and procedures compare favorably with the guidelines of the proposal." Texaco, Inc. (Mar. 28, 1991). A proposal requesting a report has been "substantially implemented" where the company has made the subject matter of the requested report available publicly, such as on its website. See, e.g., Mondelez International, Inc. (Mar. 7, 2014) (granting relief for a proposal requesting the board to report on the company's process for identifying and analyzing potential and actual human rights risks of its operations and supply chain, where the company made relevant information available on its website).

Mallinckrodt has been at the forefront in developing a comprehensive, industry-leading opioid anti-diversion program by working with its customer-distributors, the U.S. Drug Enforcement Agency ("DEA") and law enforcement to prevent prescription drug diversion, misuse and abuse. Mallinckrodt has a demonstrated record of meeting and exceeding the requirements of federal and state laws governing the manufacturing, sale and distribution of controlled substances. As disclosed on the Company's website (and periodically updated as applicable),[4] the Company has implemented a multi-pronged approach to address the abuse of prescription opioids, including:

[4] Mallinckrodt plc, Responsible Use Programs, available at: https://www.mallinckrodt.com/corporate-responsibility/safe-use-initiatives.

- Purchase and donation of more than 1.5 million drug deactivation pouches to help combat abuse of prescription pain medications. Through this initiative, families can actively address concerns with the responsible use of pain medications, patient safety and responsible drug disposal. The pouch-based systems deactivate prescription drugs and render chemical compounds safe for landfills;

- Supported improvement of integration of federal and state prescription drug monitoring programs and strongly advocated in support of such a program in Missouri;

- Enhanced addiction rehabilitation and drug take-back programs, including provision of drop boxes to local law enforcement in communities where major Company sites reside;

- Collaboration with law enforcement to help prevent misuse and diversion, including by: (i) providing no-cost placebo tablets of Mallinckrodt opioids to officers and prosecutors for use in law enforcement operations, (ii) attacking pharmacy robberies through tracking devices in selected "dummy" bottles that look like the Company's product and (iii) contributing testimony on behalf of the prosecution in drug diversion cases;

- Improving stakeholder education for patients, providers and the public at large, including education initiatives validated by measurable outcomes;

- Partnering with stakeholders and strategically aligned third-party organizations, in part through founding the Anti-Diversion Industry Working Group, a collective of leading manufacturers and distributors of controlled substances coming together to collaborate and share best practices with the purpose of exceeding DEA obligations for opioid anti-diversion programs; and

- Joining the Massachusetts Health & Hospital Association in June 2017 to announce the release of the Pain Stewardship Program (PSP) for providers and clinical staff. Developed in collaboration with a multidisciplinary team of expert advisors, the mission of the PSP is to educate hospital stakeholders on multimodal analgesia-based acute pain management to support improvements in in-hospital opioid use, length of stay and satisfaction with treatment. Sponsored by Mallinckrodt, the program provides—at no charge—evidence-based, educational

pain management tools to help assess current hospital protocols and identify areas for improvement.[5]

Additionally, Mallinckrodt has already made a variety of other public disclosures about these matters. Significantly, in September 2017, Mallinckrodt published six (6) integrated policy initiatives to address opioid abuse and misuse.[6] In its most recent annual report, Mallinckrodt disclosed the various compliance programs it has established, including ongoing compliance training programs for all employees and a twenty four (24) hour ethics and compliance reporting hotline with a strict non-retaliation policy.[7] With respect to controlled substances in particular, the Company disclosed that "[w]e have also implemented a comprehensive controlled substances compliance program, including anti-diversion efforts and we regularly assist federal, state and local law enforcement and prosecutors in the U.S. by providing information and testimony on our products and placebos for use by the DEA and other law enforcement agencies in investigations and at trial. As part of this program, we also work with some of our customers to help develop and implement what we believe are best practices for SOM and other anti-diversion activities."

To the extent the Proposal is viewed as a request for the Board to oversee risk management, the Proposal has been substantially implemented and, therefore, may be excluded under Rule 14a-8(i)(10). As disclosed in the Company's Proxy Statement for its 2017 Annual General Meeting of Shareholders (the "2017 Proxy Statement"), "[a] fundamental part of risk management is not only understanding the risks we face and what steps management is taking to manage those risks, but also understanding what level of risk is appropriate for us. The involvement of the full Board in approving our business strategy is a key part of its assessment of management's appetite for risk and the determination of what constitutes an appropriate level of risk for us."[8] The 2017 Proxy Statement also describes the committees of the Board and their and management's roles in regularly reviewing and monitoring key risks, including financial and reputational risks related to the sale of opioid-containing products, which is directly responsive for the Proposal's request for a report on Board oversight of such risks.

The foregoing disclosures from the 2017 Proxy Statement, as well as the Company's publicly available Corporate Governance Guidelines, and Board committee charters, make clear that the Board and its committees have responsibility for overseeing reputational and

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[5] News Release of Mallinckrodt plc (Jun. 21, 2017), available at: https://www.mallinckrodt.com/about/news-and-media/2282198.

[6] Mallinckrodt plc, A Prescription for America's Opioid Epidemic: Six Integrated Policy Initiatives to Address Opioid Abuse and Misuse, available at: http://www.mallinckrodt.com/Content/files/MNK%20Prescription%20Drug%20Abuse%20Policy%20Proposals%209-21-17.pdf.

[7] Mallinckrodt plc, Form 10-K for the fiscal year ended September 30, 2016, available at: https://www.sec.gov/Archives/edgar/data/1567892/000156789216000098/mnk10-k93016.htm.

[8] Mallinckrodt plc, Definitive Proxy Statement on Schedule 14A, filed Jan. 18, 2017, page 12.

financial risks across the spectrum, including its manufacture and sale of opioid products. The Company does not believe that it is necessary or common to specifically reference risks related to particular categories of products in corporate governance documents, especially when a company sells many types of products across a variety of businesses and the opioid related products constitute a notable minority of the Company's business.

CONCLUSION

Based on the foregoing analyses, the Company respectfully requests the Staff's concurrence with the Company's view or, alternatively, that the Staff confirm that it will not recommend any enforcement action if the Company excludes the Proposal and the Supporting Statement from the 2018 Proxy Materials.

If we can be of any further assistance in this matter, please do not hesitate to call the undersigned at (212) 403-1005. If the Staff is unable to concur with the Company's conclusions without additional information or discussions, the Company respectfully requests the opportunity to confer with members of the Staff prior to the issuance of any written response to this letter. In accordance with Staff Legal Bulletin No. 14F, Part F (Oct. 18, 2011), please send your response to this letter by email to VGoldfeld@wlrk.com.

Very truly yours,

Victor Goldfeld

Enclosures

cc: Michael-Bryant Hicks, Mallinckrodt plc
Stephanie D. Miller, Mallinckrodt plc

Exhibit A

September 15, 2017

Stephanie D. Miller, Vice President and Corporate Secretary
Mallinckrodt plc
3 Lotus Park
The Causeway
Staines-Upon-Thames, Surry TW18 3AG
United Kingdom

Dear Ms. Miller:

Mercy Investment Services, Inc. (Mercy), as the investment program of the Sisters of Mercy of the Americas has long been concerned not only with the financial returns of its investments, but also with the social and ethical implications of its investments. We believe that a demonstrated corporate responsibility in matters of the environment, social and governance concerns fosters long-term business success. Mercy Investment Services, Inc., a long-term investor, is currently the beneficial owner of shares of Mallinckrodt plc.

Mercy is requesting Mallinckrodt plc to report to shareholders by September 30, 2018, on the governance measures Mallinckrodt has implemented since 2012 to more effectively monitor and manage financial and reputational risks related to the opioid crisis in the U.S.

Mercy Investment Services, Inc., is co-filing the enclosed shareholder proposal with Providence Trust for inclusion in the 2018 proxy statement, in accordance with Rule 14a-8 of the General Rules and Regulations of the Securities Exchange Act of 1934. Mercy Investment Services, Inc. has been a shareholder continuously for more than one year and will continue to invest in at least the requisite number of shares for proxy resolutions through the annual shareholders' meeting. A representative of the filers will attend the Annual Meeting to move the resolution as required by SEC rules. The verification of ownership is being sent to you separately by our custodian, a DTC participant. Providence Trust may withdraw the proposal on our behalf. We respectfully request direct communications from Mallinckrodt plc, and to have our supporting statement and organization name included in the proxy statement.

Although we prefer to resolve our concerns through dialogue rather than the formal resolution process, we are filing today to assure our shareholder rights are preserved. We commend the company for its openness to dialogue with Mercy Investment Services and other investors and look forward to having productive conversations with the company in the future. Please direct your responses to me via my contact information below.

Best regards,

Donna Meyer

Donna Meyer
Director, Shareholder Advocacy
713-667-1715
dmeyer@mercyinvestments.org

RESOLVED, that shareholders of Mallinckrodt plc ("Mallinckrodt") urge the Board of Directors (the "Board") to report to shareholders by September 30, 2018 on the governance measures Mallinckrodt has implemented since 2012 to more effectively monitor and manage financial and reputational risks related to the opioid crisis in the U.S., given Mallinckrodt's sale of opioid medications and active pharmaceutical ingredients in opioid medications, including whether Mallinckrodt has assigned responsibility for such monitoring to the Board or one or more Board committees, revised senior executive compensation metrics or policies, adopted or changed mechanisms for obtaining input from stakeholders, or altered policies or processes regarding company political activities.

The report should be prepared at reasonable cost and should omit confidential and proprietary information.

SUPPORTING STATEMENT

Opioid abuse is undeniably a public health crisis: The Centers for Disease Control and Prevention reported that in 2015, opioid abuse caused more than 33,000 deaths in the U.S., or 91 people per day. The economic and social effects of the opioid crisis have been profound. Opioid use and dependency, according to a recent Goldman Sachs study, is a key factor in why many men of prime working age in the U.S. are unable or unwilling to find work. Costs associated with opioid abuse strain patients, health care payers and state and local budgets.

Mallinckrodt accounted for 43.8 million of the 236 million opioid prescriptions filled in 2016, according to IMS Health, and has come under scrutiny for its sales and marketing practices. Mallinckrodt recently settled federal claims involving its sales and distribution of controlled substances, including opioids. On July 27, 2017, Mallinckrodt received a subpoena from the U.S. Department of Justice seeking information on the company's promotional practices for, and sales of, opioid products.

Attention has focused on Mallinckrodt's increased political spending and lobbying amidst public outcry over the opioid crisis and demands for more regulation and enforcement. (E.g., https://www.nytimes.com/2017/07/21/business/a-drug-maker-spends-big-in-washington-to-make-itself-heard.html?mcubz=1)

Mallinckrodt discloses on its website a number of steps it has taken in the last several years to combat diversion and illegal sale of opioids, including founding the Anti-Diversion Industry Working Group. We believe, however, that Board-level oversight and governance reforms can play an important role in effectively addressing opioid-related risks and that shareholders would benefit from a fuller understanding of governance mechanisms serving that function.

For example, it is not clear from Mallinckrodt's Board committee charters or proxy statement whether a specific Board committee monitors opioid-related financial and reputational risks, though the Compliance Committee charter mentions potentially opioid-related matters such as DEA and off-label promotion compliance. As well, Mallinckrodt's most recent proxy statement asserts that "building a patient- and customer centric high-performing organization" is among the "strategic imperatives" used to assess named executive officer individual performance for incentive compensation purposes, but does not indicate whether any opioid-related objectives, such as promoting ethical conduct or working effectively with stakeholders, were considered.

We urge shareholders to vote for this proposal.

BNY MELLON

September 15, 2017

Stephanie D. Miller
Vice President and Corporate Secretary
Mallinckrodt plc
3 Lotus Park
The Causeway
Staines-Upon-Thames, Surry TW18 3AG
United Kingdom
Phone: +44 017 8463 6700

Re: Mercy Investment Services Inc.

Dear Ms. Miller,

This letter will certify that as of September 15, 2017, The Bank of New York Mellon held for the beneficial interest of Mercy Investment Services Inc., 38 shares of Mallinckrodt Plc and that such beneficial ownership has existed continuously for more than one year as of September 15, 2017. Also, please be advised, The Bank of New York Mellon is a DTC Participant, whose DTC number is 0901.

If you have any questions please feel free to give me a call.

Sincerely,

Thomas J. McNally
Vice President, Service Director
BNY Mellon Asset Servicing

Phone: (412) 234-8822
Email: thomas.mcnally@bnymellon.com

PROVIDENCE TRUST
SAN ANTONIO, TEXAS

September 15, 2017

Stephanie D. Miller, Vice President and Corporate Secretary
Mallinckrodt plc
3 Lotus Park
The Causeway
Staines-Upon-Thames, Surry TW18 3AG
United Kingdom

Dear Ms. Miller:

Providence Trust has long been concerned not only with the financial returns of its investments, but also with the social and ethical implications of its investments. We believe that a demonstrated corporate responsibility in matters of the environment, social and governance concerns fosters long-term business success. Providence Trust, a long-term investor, is currently the beneficial owner of shares of Mallinckrodt plc.

Providence Trust is requesting Mallinckrodt plc to report to shareholders by September 30, 2018, on the governance measures Mallinckrodt has implemented since 2012 to more effectively monitor and manage financial and reputational risks related to the opioid crisis in the U.S.

Providence Trust is filing the enclosed shareholder proposal for inclusion in the 2018 proxy statement, in accordance with Rule 14a-8 of the General Rules and Regulations of the Securities Exchange Act of 1934. Providence Trust has been a shareholder continuously for more than one year holding at least $2,000 in market value, and will continue to invest in at least the requisite number of shares for proxy resolutions through the annual shareholders' meeting. A representative of the filers will attend the Annual Meeting to move the resolution as required by SEC rules. The verification of ownership is enclosed and is also being sent to you separately by our custodian, a DTC participant. We respectfully request direct communications from Mallinckrodt, and to have our supporting statement and organization name included in the proxy statement.

Although we prefer to resolve our concerns through dialogue rather than the formal resolution process, we are filing today to assure our shareholder rights are preserved. We look forward to having productive conversations with the company. Please direct your responses to Donna Meyer, Director, Shareholder Advocacy, Mercy Investment Services, Inc., 713-667-1715, dmeyer@mercyinvestments.org.

Best regards,

Sister Ramona Bezner, CDP
Trustee

The Quantitative Group
755 E Mulberry Ave
Suite 300
San Antonio, TX 78212
tel 210 277 4400
fax 210 735 1150
toll free 800 733 1150

Graystone Consulting℠

September 15, 2017

Stephanie D. Miller, Vice President and Corporate Secretary
Mallinckrodt plc
3 Lotus Park
The Causeway
Staines-Upon-Thames
Surry TW18 3AG
United Kingdom

Re: Providence Trust

Dear Ms. Miller,

This letter will certify that as of September 15, 2017, Morgan Stanley held for the beneficial interest of Providence Trust, 898 shares of Mallinckrodt plc.

We confirm that Providence Trust has beneficial ownership of at least $2,000 in market value of the voting securities of Mallinckrodt plc, and that such beneficial ownership has existed continuously for one or more years in accordance with rule 14a-8(a)(1) of the Securities Exchange Act of 1934.

Further, it is Providence Trust intent to hold at least $2,000 in market value through the next annual meeting.

Please be advised, Morgan Stanley, Inc. is a DTC Participant, whose DTC number is 0015.

If you have any questions, please feel free to give me a call at (210) 366-6660

Sincerely,

Heidi Siller
Registered Associate
The Quantitative Group at Graystone Consulting
A Business of Morgan Stanley

RESOLVED, that shareholders of Mallinckrodt plc ("Mallinckrodt") urge the Board of Directors (the "Board") to report to shareholders by September 30, 2018 on the governance measures Mallinckrodt has implemented since 2012 to more effectively monitor and manage financial and reputational risks related to the opioid crisis in the U.S., given Mallinckrodt's sale of opioid medications and active pharmaceutical ingredients in opioid medications, including whether Mallinckrodt has assigned responsibility for such monitoring to the Board or one or more Board committees, revised senior executive compensation metrics or policies, adopted or changed mechanisms for obtaining input from stakeholders, or altered policies or processes regarding company political activities.

The report should be prepared at reasonable cost and should omit confidential and proprietary information.

SUPPORTING STATEMENT

Opioid abuse is undeniably a public health crisis: The Centers for Disease Control and Prevention reported that in 2015, opioid abuse caused more than 33,000 deaths in the U.S., or 91 people per day. The economic and social effects of the opioid crisis have been profound. Opioid use and dependency, according to a recent Goldman Sachs study, is a key factor in why many men of prime working age in the U.S. are unable or unwilling to find work. Costs associated with opioid abuse strain patients, health care payers and state and local budgets.

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We urge shareholders to vote for this proposal.

Catholic Health Initiatives
Imagine better health.℠

198 Inverness Drive West
Englewood, CO 80112

P 303.298.9100
F 303.298.9690
catholichealthinitiatives.org

September 19, 2017

Stephanie D. Miller, Vice President and Corporate Secretary
Mallinckrodt plc
3 Lotus Park
The Causeway
Staines-Upton-Thames, Surry TW18 3AG
United Kingdom

Dear Ms. Miller:

Catholic Health Initiatives is one of the largest Catholic health care systems in the country, with operations in 17 states comprised of 100 hospitals, including four academic health centers and major teaching hospitals as well as 30 critical-access facilities; community health-services organizations; accredited nursing colleges; home-health agencies; living communities; and other facilities that span the inpatient and outpatient continuum of care.

As a religiously sponsored organization, Catholic Health Initiatives seeks to reflect its mission, vision and values in its investment decisions. Catholic Health Initiatives has significant concerns about the national opioid crisis. We request Mallinckrodt plc, report to shareholders by September 30, 2018, on the governance measures Mallinckrodt has implemented since 2012 to more effectively monitor and manage financial and reputational risks related to the opioid crisis in the U.S.

Catholic Health Initiatives is the beneficial owner of over $2000 worth of common stock in Mallinckrodt plc. Through this letter we notify the company of our intention to file the enclosed resolution. We present it for inclusion in the proxy statement for action at the next stockholders meeting in accordance with Rule 14(a)(8) of the General Rules and Regulations of the Securities and Exchange Act of 1934.

Verification of our ownership of this stock for at least one year is enclosed. We intend to maintain ownership through the date of the annual meeting. There will be a representative present at the stockholders meeting to present this resolution as required by the SEC Rules.

I will serve as the contact for Catholic Health Initiatives and can be reached at 303-383-2693. We are filing this resolution along with other concerned investors including primary filer, Providence Trust. It is our tradition as a religiously sponsored organization to seek dialogue with companies on the issue in the resolution offered to the shareholders. We hope that a discussion of this sort is of interest to you as well.

Sincerely,

Colleen Scanlon
Senior Vice President & Chief Advocacy Officer
Attachments

CS/dm
cc: Donna Meyer, Mercy Investment Services
Julie Wokaty, Interfaith Center on Corporate Responsibility

Financial & Reputational Risks Related to the Opioid Crisis

2018 – Mallinckrodt Group Inc.

RESOLVED, that shareholders of Mallinckrodt plc ("Mallinckrodt") urge the Board of Directors (the "Board") to report to shareholders by September 30, 2018 on the governance measures Mallinckrodt has implemented since 2012 to more effectively monitor and manage financial and reputational risks related to the opioid crisis in the U.S., given Mallinckrodt's sale of opioid medications and active pharmaceutical ingredients in opioid medications, including whether Mallinckrodt has assigned responsibility for such monitoring to the Board or one or more Board committees, revised senior executive compensation metrics or policies, adopted or changed mechanisms for obtaining input from stakeholders, or altered policies or processes regarding company political activities.

The report should be prepared at reasonable cost and should omit confidential and proprietary information.

Supporting Statement: Opioid abuse is undeniably a public health crisis: The Centers for Disease Control and Prevention reported that in 2015, opioid abuse caused more than 33,000 deaths in the U.S., or 91 people per day. The economic and social effects of the opioid crisis have been profound. Opioid use and dependency, according to a recent Goldman Sachs study, is a key factor in why many men of prime working age in the U.S. are unable or unwilling to find work. Costs associated with opioid abuse strain patients, health care payers and state and local budgets.

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We urge shareholders to vote for this proposal.

BNY MELLON

September 19, 2017

Jennifer Neppel
Director, Cash & Investments
Catholic Health Initiatives
198 Inverness Drive West
Suite 800
Englewood, CO 80112

RE: Shareholder Activism Account Number *** – Mallinckrodt PLC

Dear Jennifer,

This letter is in response to your request for confirmation that Catholic Health Initiatives currently holds 82 shares of Mallinckrodt PLC in the CHI Operating Investment Program Limited Partnership.

Catholic Health Initiatives has continuously held these shares of stock for at least one year prior to and including submission of CHI's letter of proposal and such investment has a market value greater than $2,000.

This security is currently held by The Bank of New York Mellon for Catholic Health Initiatives in our nominee name at the Depository Trust Company. This letter is a statement of The Bank of New York Mellon Corporation as record holder of the above referenced common stock.

Should you have any questions, please contact me at 412.234.8014.

Best regards,

Nina Caruso
Vice President, Service Director
The Bank of New York Mellon
BNY Mellon Center
Suite 4040
Pittsburgh, PA 15258

*** FISMA & OMB Memorandum M-07-16

EXHIBIT 11

Mallinckrodt plc Receives FDA Approval For XARTEMIS XR (oxycodone hydrochloride and acetaminophen) Extended-Release Tablets (CII)

First and only extended-release oxycodone/acetaminophen medication approved for acute pain severe enough to require opioid treatment

Built on patented Mallinckrodt formulation platform

March 12, 2014 08:30 AM Eastern Daylight Time

DUBLIN--(BUSINESS WIRE)--Mallinckrodt plc (NYSE: MNK) today announced that the U.S. Food and Drug Administration (FDA) has approved XARTEMIS™ XR (oxycodone hydrochloride and acetaminophen) Extended-Release Tablets (CII), previously known as MNK-795, for the management of acute pain severe enough to require opioid treatment and in patients for whom alternative treatment options (e.g., non-opioid analgesics) are ineffective, not tolerated or would otherwise be inadequate. XARTEMIS XR is the first and only extended-release oral combination of two clinically proven pain medications -- oxycodone and acetaminophen.

XARTEMIS XR has both immediate- and extended-release components: formulated to provide onset of pain relief in less than one hour and to allow twice daily dosing. The product's release profile combines Mallinckrodt's newly patented technology, including design, formulation, pharmacokinetic and release characteristics, and Depomed's advanced Acuform® drug delivery technology.

The approval is based, in part, on the pivotal Phase 3 efficacy study conducted in an acute post-surgical pain model. XARTEMIS XR met the study's primary endpoint and showed statistically significant improvement in pain scores compared to placebo from baseline over 48 hours.

In addition to the efficacy study, Mallinckrodt conducted extensive lab testing and a human abuse liability study with XARTEMIS XR. Data from Mallinckrodt's studies related to the product were described in 15 scientific presentations at PAINWeek, held September 4-7, 2013. While the approved label for XARTEMIS XR does not include abuse-deterrent language, Mallinckrodt will continue working closely with the FDA to develop more data to characterize abuse-deterrence features of XARTEMIS XR and other products utilizing this technology platform. The company is conducting additional studies and will be providing additional data in the near future.

Pain that is uncontrolled or unmanaged results in ongoing and very significant costs to U.S. businesses in terms of lost productivity. In 2010, there were over 102 million surgical procedures ordered or performed at office visits.[1] That same year, there were 51 million inpatient surgeries performed.[2] The Institute of Medicine reported in 2011 that 80 percent of patients undergoing surgery experience postoperative pain. Of these, 88 percent report the pain is moderate, severe or extreme.[3]

"Acute pain doesn't last for only four to six hours, and neither should its treatment. With the extended-release profile of XARTEMIS XR, patients may not need to wake in the night to take a dose," said Nathaniel Katz, MD, MS, Adjunct Assistant Professor of Anesthesia at Tufts University School of Medicine. "A long-acting combination analgesic that can effectively deliver oxycodone and acetaminophen for acute pain patients experiencing pain throughout the day and night is a welcome addition to the treatment landscape."

"The FDA approval of XARTEMIS XR exemplifies Mallinckrodt's dedication to developing and providing new treatment options for people with pain," said Mark Trudeau, President and Chief Executive Officer of Mallinckrodt. "Mallinckrodt remains committed to continuing its work to develop innovative formulations for our product lines to help ensure access to appropriate pain treatment for the millions of patients suffering from acute pain, and we will continue to work closely with the FDA as we engage in further development programs for XARTEMIS XR and other products utilizing this technology platform."

Mallinckrodt is dedicated to providing quality medications for treatment of patients with pain and equally committed to fighting the problems of opioid misuse and abuse. The company supports a broad range of programs that encourage and support only appropriate use of pain medications, and we address diversion and abuse through a multidimensional approach that includes educational efforts, monitoring for suspicious orders of controlled substances, drug take-back programs and research into abuse-deterrent technologies.

To support the appropriate use of XARTEMIS XR and other Mallinckrodt products, the company:

1. ***Provides a range of educational resources*** *for patients, physicians and pharmacists, including education initiatives validated by measurable outcomes.*

2. ***Certifies its territory representatives*** *following completion of robust education and training on all safe use initiatives for XARTEMIS XR.*
3. ***Addresses the safe and environmentally responsible disposal of unused XARTEMIS XR and other prescription medications*** *through a unique adsorption technology to render the drugs inactive and unusable.*
4. ***Maintains a comprehensive anti-diversion program*** *to detect potential misuse, abuse and diversion of Mallinckrodt products including XARTEMIS XR.*

XARTEMIS™ XR (oxycodone HCl and acetaminophen) Extended-Release Tablets, for oral use, CII

INDICATIONS AND USAGE

XARTEMIS™ XR (oxycodone HCl and acetaminophen) Extended-Release Tablets (CII) is indicated for the management of acute pain severe enough to require opioid treatment and for which alternative treatment options are inadequate. Because of the risks of addiction, abuse, misuse, overdose, and death with opioids, even at recommended doses, reserve XARTEMIS XR for use in patients for whom alternative treatment options (e.g., non-opioid analgesics) are ineffective, not tolerated, or would be otherwise inadequate.

IMPORTANT RISK INFORMATION

WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING

RESPIRATORY DEPRESSION; ACCIDENTAL EXPOSURE; NEONATAL OPIOID

WITHDRAWAL SYNDROME; and HEPATOTOXICITY

Addiction, Abuse, and Misuse

XARTEMIS XR exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing XARTEMIS XR, and monitor all patients regularly for the development of these behaviors or conditions.

Life-threatening Respiratory Depression

Serious, life-threatening, or fatal respiratory depression may occur with use of XARTEMIS XR. Monitor for respiratory depression, especially during initiation of XARTEMIS XR or following a dose increase. Instruct patients to swallow XARTEMIS XR tablets whole; crushing, chewing, or dissolving XARTEMIS XR can cause rapid release and absorption of a potentially fatal dose of oxycodone.

Accidental Exposure

Accidental ingestion of XARTEMIS XR, especially in children, can result in a fatal overdose of oxycodone.

Neonatal Opioid Withdrawal Syndrome

Prolonged use of XARTEMIS XR during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

Hepatotoxicity

XARTEMIS XR contains acetaminophen. Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed the maximum daily limit, and often involve more than one acetaminophen-containing product.

CONTRAINDICATIONS

- XARTEMIS XR is contraindicated in patients with:
  - known hypersensitivity to oxycodone, acetaminophen, or any other component of this product.
  - significant respiratory depression.
  - acute or severe bronchial asthma or hypercarbia.
  - known or suspected paralytic ileus.

WARNINGS AND PRECAUTIONS

- XARTEMIS XR contains oxycodone, a Schedule II controlled substance. As an opioid, XARTEMIS XR exposes users to the risks of addiction, abuse, and misuse. Abuse or misuse of XARTEMIS XR by crushing, chewing, snorting, or injecting the dissolved product will result in the uncontrolled delivery of the oxycodone and can result in

overdose and death. With intravenous abuse, the inactive ingredients in XARTEMIS XR can result in death, local tissue necrosis, infection, pulmonary granulomas, and increased risk of endocarditis and valvular heart injury. Parenteral drug abuse is commonly associated with transmission of infectious diseases such as hepatitis and HIV.

- Serious, life-threatening, or fatal respiratory depression has been reported with the use of opioids, even when used as recommended. While serious, life-threatening, or fatal respiratory depression can occur at any time during the use of XARTEMIS XR, the risk is greatest during the initiation of therapy or following a dose increase. Life-threatening respiratory depression is more likely to occur in elderly, cachectic, or debilitated patients as they may have altered pharmacokinetics or altered clearance compared to younger, healthier patients. In patients with significant chronic obstructive pulmonary disease or cor pulmonale, and patients having a substantially decreased respiratory reserve, hypoxia, hypercapnia, or preexisting respiratory depression, XARTEMIS XR may decrease respiratory drive to the point of apnea.
- Hypotension, profound sedation, coma, respiratory depression, and death may result if XARTEMIS XR is used concomitantly with alcohol or other central nervous system (CNS) depressants.
- The risk of acute liver failure is higher in individuals with underlying liver disease and in individuals who ingest alcohol while taking acetaminophen.
- Rarely, acetaminophen may cause serious skin reactions such as acute generalized exanthematous pustulosis (AGEP), Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal.
- The respiratory depressant effects of narcotics and their capacity to elevate cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury, other intracranial lesions, or a pre-existing increase in intracranial pressure.
- Oxycodone may cause severe hypotension particularly in individuals whose ability to maintain blood pressure has been compromised by a depleted blood volume, or after concurrent administration with drugs which compromise vasomotor tone such as phenothiazines.
- Due to the potential for acetaminophen hepatotoxicity at doses higher than 4000 milligrams/day, XARTEMIS XR should not be used concomitantly with other acetaminophen-containing products.
- Hypersensitivity and anaphylaxis associated with use of acetaminophen have been reported. Clinical signs included swelling of the face, mouth, and throat, respiratory distress, urticaria, rash, pruritus, and vomiting.
- Due to characteristics of the formulation that cause the tablets to swell and become sticky when wet, consider use of an alternative analgesic in patients who have difficulty swallowing and patients at risk for underlying GI disorders resulting in a small gastrointestinal lumen. Instruct patients not to pre-soak, lick or otherwise wet XARTEMIS XR tablets prior to placing in the mouth, and to take one tablet at a time with enough water to ensure complete swallowing immediately after placing in mouth.
- Opioids diminish propulsive peristaltic waves in the gastrointestinal tract and decrease bowel motility. Oxycodone may cause spasm of the Sphincter of Oddi and should be used with caution in patients with biliary tract disease, including acute pancreatitis.
- Since the CYP3A4 isoenzyme plays a major role in the metabolism of XARTEMIS XR, drugs that alter CYP3A4 activity may cause changes in clearance of oxycodone which could lead to changes in oxycodone plasma concentrations.
- XARTEMIS XR may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery. The patient using this drug should be cautioned accordingly.

ADVERSE REACTIONS

- Serious adverse events may include respiratory depression and hepatotoxicity.
- Common adverse events include nausea, dizziness, headache, vomiting, constipation and somnolence.

USE IN SPECIFIC POPULATIONS

- Pregnancy: Opioids cross the placenta and may produce respiratory depression and psycho-physiologic effects in neonates. Prolonged use of XARTEMIS XR during pregnancy can result in withdrawal signs in the neonate, which can be life threatening.
- Breast feeding: Oxycodone is present in human milk and may result in accumulation and toxicities such as sedation and respiratory depression in some infants. Acetaminophen is present in human milk in small quantities.
- Pediatrics: Safety and effectiveness in pediatric patients under the age of 18 years have not been established.

See Full Prescribing Information for additional Important Risk Information including boxed warning.

About XARTEMIS™ XR

XARTEMIS XR is an extended-release oral formulation of oxycodone hydrochloride and acetaminophen with immediate-release and extended-release components. It is not interchangeable with other oxycodone/acetaminophen products because of differing pharmacokinetic profiles that affect the frequency of administration. XARTEMIS XR is a schedule II controlled substance.

About Mallinckrodt

Mallinckrodt is a global specialty pharmaceutical business that develops, manufactures, markets and distributes specialty pharmaceutical products and medical imaging agents. The company's Specialty Pharmaceuticals segment includes branded and specialty generic drugs and active pharmaceutical ingredients, and the Global Medical Imaging segment includes contrast media and nuclear imaging agents. Mallinckrodt has approximately 5,500 employees worldwide and a commercial presence in roughly 70 countries. The company's fiscal 2013 revenue totaled $2.2 billion. To learn more about Mallinckrodt, visit www.mallinckrodt.com.

References

[1]CDC/NCHS, National Ambulatory Medical Care Survey. Accessed 2/25/2014. http://www.cdc.gov/nchs/data/ahcd/namcs_summary/2010_namcs_web_tables.pdf.

[2]CDC, FastStats, accessed 2/25/14: http://www.cdc.gov/nchs/fastats/insurg.htm.

[3]Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. Committee on Advancing Pain Research, Care, and Education; Institute of Medicine. 2011.

FORWARD-LOOKING STATEMENTS

Any statements contained in this communication that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include, but are not limited to, statements about future financial condition and operating results, economic, business, competitive and/or regulatory factors affecting our business. Any forward-looking statements contained herein are based on our management's current beliefs and expectations, but are subject to a number of risks, uncertainties and changes in circumstances, which may cause actual results or company actions to differ materially from what is expressed or implied by these statements. The factors that could cause actual future results to differ materially from current expectations include, but are not limited to, our ability to receive procurement and production quotas granted by the U.S. Drug Enforcement Administration, our ability to obtain and/or timely transport molybdenum-99 to our technetium-99m generator production facilities, customer concentration, cost-containment efforts of customers, purchasing groups, third-party payors and governmental organizations, our ability to successfully develop or commercialize new products, our ability to protect intellectual property rights, competition, our ability to integrate acquisitions of technology, products and businesses, product liability losses and other litigation liability, the reimbursement practices of a small number of large public or private issuers, complex reporting and payment obligation under healthcare rebate programs, changes in laws and regulations, conducting business internationally, foreign exchange rates, material health, safety and environmental liabilities, litigation and violations, information technology infrastructure and restructuring activities. These and other factors are identified and described in more detail in the "Risk Factors" section of Mallinckrodt's Annual Report on Form 10-K for the fiscal year ended September 27, 2013 and in subsequent filings. We disclaim any obligation to update these forward-looking statements other than as required by law.

Contacts

Mallinckrodt plc
Lynn Phillips, 314-654-3263
Manager, Media Relations
lynn.phillips@mallinckrodt.com
or
Meredith Fischer, 314-654-3318
Senior Vice President, Communications
meredith.fischer@mallinckrodt.com
or
John Moten, 314-654-6650
Vice President, Investor Relations
john.moten@mallinckrodt.com

EXHIBIT 15

Jeff Kilper • 3rd

Finance Leader | Senior Operations Controller | jeffkilper@gmail.com

Saint Louis, Missouri

Mallinckrodt Pharmaceuticals (Spun-off from Covidine...

University of Missouri-Saint Louis

See contact info

500+ connections

Message ···

Senior-level Finance Leader accomplished at optimizing business performance and strategically driving change including restructurings, acquisitions, divestitures and business integrations. Relentlessly pursue exceptional results through collaboration with cross-functional leaders; utilizing critical thinking and insightful decision making to solve complex problems.

Integrated four (4) acquisitions, $2 billion total revenue, over a 2-year period, delivering operations and commercial finance due diligence and integration support. Saved $100 million in manufacturing costs after transforming the manufacturing network of 10 facilities working with a cross-functional team as the Finance lead.

Leadership | Strategic Planning | Business Partnership | P&L Management | CPA
Acquisitions | Business Integration | Restructuring | Divestitures | Due Diligence
Process Improvement | Process Streamlining | Cost Reduction | Lean Manufacturing
Strategic Initiatives | Contracting Strategies| Consignment Purchasing | Planning
Financial Forecasting | Financial Analysis | Financial Reporting | Finance Integration
Change Management | Critical Thinking | Insightful Decision Making | Problem Solving
Lean Manufacturing | Six Sigma | Continuous Improvement | Operational Excellence
Working Capital | Inventory Management | Business Process Improvement

Show less

Experience

Senior Director Finance, Specialty Generics

Mallinckrodt Pharmaceuticals (Spun-off from Covidine 2013)

2016 – Present · 3 yrs

Webster Groves, Missouri

Leading a direct staff of 10 and a total organization of 24 finance professionals providing full range of financial planning activities for a $1 billion generics business with four (4) manufacturing facilities.

Transitioned business to a stand-alone operating model that includes commercial operations, manufacturing operations, research and development and SG&A functions. Planned divestiture for $1 billion generic division including carve-out audit, deal basis financial statements, confidential offering memorandum, third-party branded due diligence report, legal entity carve-out and due diligence with prospective buyers.

Exhibit
Mallinckrodt-Kilper-001
2-6-19 (JA)

Mallinckrodt Pharmaceuticals (Spun-off from Covidien 2013)
5 yrs

Finance Director, Hospital Therapies
2015 – 2016 · 1 yr
Greater St. Louis Area

Led a direct staff of eight (8) finance professionals providing financial planning activities for a business that grew from $300 million to $1 billion in revenue over a six (6) month period.
... See more

Finance Director, Autoimmune and Rare Diseases
2014 – 2015 · 1 yr
Greater St. Louis Area

Interim assignment - Full range of financial planning activities for a $1 billion acquisition evaluating finance processes and finance support structure.

Established business partnerships with key commercial leaders to develop a 5-yea... See more

Senior Operations Controller
2011 – 2014 · 3 yrs
Greater St. Louis Area

Led a direct staff of six (6) and a total organization of 47 finance professionals providing a full range of financial planning activities for a $1 billion Global Operations Group which included 10 pharmaceutical manufacturing facilities and 10 distribution centers located throughout The Americas and Europe.

Saved $100 million in manufacturing costs after transforming the manufacturing network of 10 facilities, working with a cross-functional team as the Finance Leader, decreasing working capital by $30 million through targeted reductions in safety stock and implementing consignment purchasing of certain raw materials.

Leadership | Strategic Planning | Business Partnership | Cross-Functional Team Leadership
Business Process Improvement | Cost Reduction | Working Capital | Inventory Management
Financial Planning | Financial Forecasting | Financial Analysis | Financial Reporting
International – 10 countries | Global Operations | Insightful Decision Making | Problem Solving See less

Show fewer roles

Covidien (Spun-off from Tyco International 2007)
9 yrs

Operations Controller
2006 – 2011 · 5 yrs
Greater St. Louis Area

Led a direct staff of nine (9) and a total organization of 38 Finance and 20 IT professionals providing a full range of financial planning activities for nine (9) pharmaceuticals manufacturing facilities located throughout The Americas and Europe.
... See more

Plant Controller, St. Louis Plant
2005 – 2006 · 1 yr
Greater St. Louis Area

Manager - Planning Analysis, St. Louis Plant
2002 – 2005 · 3 yrs
Greater St. Louis Area

Show fewer roles

Senior Financial Analyst
Tyco International
2000 – 2002 · 2 yrs
Greater St. Louis Area

1998 – 2000 · 2 yrs
Greater St. Louis Area

Senior Auditor
Birchler Mengwasser Martin Lall
1988 – 1998 · 10 yrs
Greater St. Louis Area

Show fewer experiences

Education

University of Missouri-Saint Louis
Degrees in Accounting and Finance

Skills & Endorsements

Strategic Initiatives · 1
Dale Rees has given an endorsement for this skill

Business Performance · 1
Dale Rees has given an endorsement for this skill

Business Integration · 1
Dale Rees has given an endorsement for this skill

Show more

Recommendations

Received (2) Given (0)

Dale Rees
Chief Financial Officer | Finance Leader | DaleJRees@gmail.com
December 27, 2018, Dale managed Jeff directly

Jeff's breadth of finance experience in a manufacturing environment is tough to beat! We worked closely together in manufacturing finance leadership roles for a few years and have known each other for over ten years. Jeff always impressed me with his knowledge of the business, involvement in strategic... See more

Jim Walter, CPIM
SVP of Operations and Engineering at Tinuum Group
November 8, 2018, Jim was senior to Jeff but didn't manage directly

I worked with Jeff in a variety of roles over the years. He is a fantastic financial leader and has a broad understanding of how all aspects of commercial and manufacturing areas affect the bottom line. Jeff has a tremendous grasp of the entire business and is extremely versatile. Jeff also has an audit background t... See more

Accomplishments

1 Certification
Certified Public Accountant


4
7
17
Try Premium Free for 1 Month

professionals providing a full range of financial planning activities for nine (9) pharmaceuticals manufacturing facilities located throughout The Americas and Europe.
... See more

Plant Controller, St. Louis Plant
2005 – 2006 · 1 yr
Greater St. Louis Area

Manager - Planning Analysis, St. Louis Plant
2002 – 2005 · 3 yrs
Greater St. Louis Area

Show fewer roles

Senior Financial Analyst
Tyco International
2000 – 2002 · 2 yrs
Greater St. Louis Area

Senior Auditor
Mallinckrodt (Acquired by Tyco International in 2000)
1998 – 2000 · 2 yrs
Greater St. Louis Area

Senior Auditor
Birchler Mengwasser Martin Lall
1988 – 1998 · 10 yrs
Greater St. Louis Area

Show fewer experiences

Education

UMSL
University of Missouri-Saint Louis
Degrees in Accounting and Finance

EXHIBIT 16

10-QT 1 mnk10-qt123016.htm 10-QT

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

☐ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

or

☒ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from October 1, 2016 to December 30, 2016

Commission File Number : 001-35803

Mallinckrodt public limited company
(Exact name of registrant as specified in its charter)

Ireland	**98-1088325**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

3 Lotus Park, The Causeway, Staines Upon Thames, Surrey TW18 3AG, United Kingdom
(Address of principal executive offices) (Zip Code)

Telephone: +44 017 8463 6700
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if smaller reporting company)	Smaller reporting company	☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

Indicate number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date:
Ordinary shares, $0.20 par value - 104,694,686 shares as of February 3, 2017

MALLINCKRODT PLC
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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

MALLINCKRODT PLC
CONDENSED CONSOLIDATED STATEMENTS OF INCOME
(unaudited, in millions, except per share data)

	Three Months Ended	
	December 30, 2016	December 25, 2015
Net sales	$ 829.9	$ 811.2
Cost of sales	384.1	360.3
Gross profit	445.8	450.9
Selling, general and administrative expenses	368.3	223.3
Research and development expenses	66.2	61.4
Restructuring charges, net	3.8	4.1
Non-restructuring impairment charges	214.3	—
Operating (loss) income	(206.8)	162.1
Interest expense	(91.3)	(97.8)
Interest income	0.5	0.2
Other (loss) income, net	(0.9)	2.0
(Loss) income from continuing operations before income taxes	(298.5)	66.5
Income tax benefit	(121.7)	(37.3)
(Loss) income from continuing operations	(176.8)	103.8
Income from discontinued operations, net of income taxes	23.6	107.3
Net (loss) income	$ (153.2)	$ 211.1
Basic earnings per share (Note 7):		
(Loss) income from continuing operations	$ (1.67)	$ 0.90
Income from discontinued operations	0.22	0.93
Net (loss) income	$ (1.45)	$ 1.83
Basic weighted-average shares outstanding	105.7	115.4
Diluted earnings per share (Note 7):		
(Loss) income from continuing operations	$ (1.67)	$ 0.89
Income from discontinued operations	0.22	0.92
Net (loss) income	$ (1.45)	$ 1.82
Diluted weighted-average shares outstanding	105.7	116.3

See Notes to Condensed Consolidated Financial Statements.

MALLINCKRODT PLC
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(unaudited, in millions)

	Three Months Ended	
	December 30, 2016	December 25, 2015
Net (loss) income	$ (153.2)	$ 211.1
Other comprehensive income (loss), net of tax:		
Currency translation adjustments	(21.1)	(68.1)
Unrecognized gain on derivatives, net of $- and $- tax	0.2	0.1
Unrecognized gain on benefit plans, net of ($19.3) and ($1.0) tax	34.0	1.8
Total other comprehensive income (loss), net of tax	13.1	(66.2)
Comprehensive (loss) income	$ (140.1)	$ 144.9

See Notes to Condensed Consolidated Financial Statements.

MALLINCKRODT PLC
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in millions, except share data)

	December 30, 2016	September 30, 2016
Assets		
Current Assets:		
Cash and cash equivalents	$ 342.0	$ 280.5
Accounts receivable, less allowance for doubtful accounts of $4.0 and $4.0	431.0	465.8
Inventories	350.7	335.6
Prepaid expenses and other current assets	131.9	115.9
Current assets held for sale	310.9	308.8
Total current assets	1,566.5	1,506.6
Property, plant and equipment, net	881.5	844.0
Goodwill	3,498.1	3,705.3
Intangible assets, net	9,000.5	9,182.3
Other assets	259.7	260.5
Total Assets	$ 15,206.3	$ 15,498.7
Liabilities and Shareholders' Equity		
Current Liabilities:		
Current maturities of long-term debt	$ 271.2	$ 256.3
Accounts payable	112.1	110.1
Accrued payroll and payroll-related costs	76.1	116.0
Accrued interest	68.7	80.6
Accrued and other current liabilities	658.8	550.9
Current liabilities held for sale	120.3	120.8
Total current liabilities	1,307.2	1,234.7
Long-term debt	5,880.8	5,788.7
Pension and postretirement benefits	136.4	144.9
Environmental liabilities	73.0	73.4
Deferred income taxes	2,398.1	2,581.4
Other income tax liabilities	70.4	67.7
Other liabilities	356.1	337.2
Total Liabilities	10,222.0	10,228.0
Shareholders' Equity:		
Preferred shares, $0.20 par value, 500,000,000 authorized; none issued and outstanding	—	—
Ordinary A shares, €1.00 par value, 40,000 authorized; none issued and outstanding	—	—
Ordinary shares, $0.20 par value, 500,000,000 authorized; 118,182,944 and 118,137,297 issued; 104,667,545 and 107,167,693 outstanding	23.6	23.6
Ordinary shares held in treasury at cost, 13,515,399 and 10,969,604	(919.8)	(762.6)
Additional paid-in capital	5,424.0	5,412.7
Retained earnings	529.0	682.6
Accumulated other comprehensive loss	(72.5)	(85.6)
Total Shareholders' Equity	4,984.3	5,270.7
Total Liabilities and Shareholders' Equity	$ 15,206.3	$ 15,498.7

See Notes to Condensed Consolidated Financial Statements.

MALLINCKRODT PLC
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited, in millions)

	Three Months Ended	
	December 30, 2016	December 25, 2015
Cash Flows From Operating Activities:		
Net (loss) income	$ (153.2)	$ 211.1
Adjustments to reconcile net cash provided by operating activities:		
Depreciation and amortization	203.2	206.0
Share-based compensation	11.0	8.5
Deferred income taxes	(204.3)	(108.9)
Non-cash impairment charges	214.3	—
Gain on disposal of discontinued operations	—	(97.0)
Other non-cash items	(0.7)	4.1
Changes in assets and liabilities, net of the effects of acquisitions:		
Accounts receivable, net	36.5	68.4
Inventories	(26.3)	(14.5)
Accounts payable	5.4	(13.0)
Income taxes	0.6	82.3
Other	109.1	(35.6)
Net cash provided by operating activities	195.6	311.4
Cash Flows From Investing Activities:		
Capital expenditures	(65.2)	(49.0)
Acquisitions and intangibles, net of cash acquired	(1.8)	—
Proceeds from disposal of discontinued operations, net of cash	—	264.0
Restricted cash	—	(0.1)
Other	(10.2)	0.7
Net cash (used in) provided by investing activities	(77.2)	215.6
Cash Flows From Financing Activities:		
Issuance of external debt	190.0	62.0
Repayment of external debt and capital leases	(86.7)	(129.6)
Debt financing costs	—	(0.1)
Proceeds from exercise of share options	0.4	3.6
Repurchase of shares	(158.8)	(275.4)
Other	1.2	(30.0)
Net cash (used in) financing activities	(53.9)	(369.5)
Effect of currency rate changes on cash	(3.0)	(1.5)
Net increase in cash and cash equivalents	61.5	156.0
Cash and cash equivalents at beginning of period	280.5	365.9
Cash and cash equivalents at end of period	$ 342.0	$ 521.9

See Notes to Condensed Consolidated Financial Statements.

MALLINCKRODT PLC
CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY
(unaudited, in millions)

	Ordinary Shares		Treasury Shares		Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Total Shareholders' Equity
	Number	Par Value	Number	Amount				
Balance at September 30, 2016	118.1	$ 23.6	11.0	$ (762.6)	$ 5,412.7	$ 682.6	$ (85.6)	$ 5,270.7
Net loss	—	—	—	—	—	(153.2)	—	(153.2)
Currency translation adjustments	—	—	—	—	—	—	(21.1)	(21.1)
Change in derivatives, net of tax	—	—	—	—	—	—	0.2	0.2
Minimum pension liability, net of tax	—	—	—	—	—	—	34.0	34.0
Share options exercised	0.1	—	—	—	0.4	—	—	0.4
Excess tax benefit from share-based compensation	—	—	—	—	(0.1)	—	—	(0.1)
Share-based compensation	—	—	—	—	11.0	—	—	11.0
Reissuance of treasury shares	—	—	—	1.6	—	(0.4)	—	1.2
Repurchase of shares	—	—	2.5	(158.8)	—	—	—	(158.8)
Balance at December 30, 2016	118.2	$ 23.6	13.5	$ (919.8)	$ 5,424.0	$ 529.0	$ (72.5)	$ 4,984.3

See Notes to Condensed Consolidated Financial Statements.

MALLINCKRODT PLC
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited, dollars in millions, except per share data and where indicated)

1. Background and Basis of Presentation

Background

Mallinckrodt plc and its subsidiaries (collectively, "Mallinckrodt" or "the Company"), is a global business that develops, manufactures, markets and distributes branded and generic specialty pharmaceutical products and therapies. Therapeutic areas of focus include autoimmune and rare disease specialty areas (including neurology, rheumatology, nephrology, ophthalmology and pulmonology); immunotherapy and neonatal respiratory critical care therapies; analgesics and hemostasis products and central nervous system drugs.

The Company operates in two reportable segments, which are further described below:

- *Specialty Brands* includes branded pharmaceutical products and therapies; and
- *Specialty Generics* includes specialty generic pharmaceuticals and active pharmaceutical ingredients ("API") consisting of biologics, medicinal opioids, synthetic controlled substances, acetaminophen and other active ingredients.

The Company owns or has rights to use the trademarks and trade names that are used in conjunction with the operation of its business. One of the more important trademarks that the Company owns or has rights to use that appears in this Transition Report on Form 10-Q is "Mallinckrodt," which is a registered trademark or the subject of pending trademark applications in the U.S. and other jurisdictions. Solely for convenience, the Company only uses the ™ or ® symbols the first time any trademark or trade name is mentioned in the following notes. Such references are not intended to indicate in any way that the Company will not assert, to the fullest extent permitted under applicable law, its rights to its trademarks and trade names. Each trademark or trade name of any other company appearing in the following discussion is, to the Company's knowledge, owned by such other company.

Basis of Presentation

The unaudited condensed consolidated financial statements have been prepared in U.S. Dollars and in accordance with accounting principles generally accepted in the U.S. ("GAAP"). The preparation of the unaudited condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amount of assets and liabilities, disclosure of contingent assets and liabilities and the reported amounts of net sales and expenses. Actual results may differ from those estimates. The unaudited condensed consolidated financial statements include the accounts of Mallinckrodt plc, its wholly-owned subsidiaries and entities in which they own or control more than fifty percent of the voting shares, or have the ability to control through similar rights. The results of entities disposed of are included in the unaudited condensed consolidated financial statements up to the date of disposal and, where appropriate, these operations have been reflected as discontinued operations. Divestitures of product lines and businesses that did not qualify as discontinued operations have been reflected in operating income. All intercompany balances and transactions have been eliminated in consolidation and, in the opinion of management, all normal recurring adjustments necessary for a fair presentation have been included in the interim results reported. The fiscal year-end balance sheet data was derived from audited consolidated financial statements, but does not include all of the annual disclosures required by GAAP; accordingly, these unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited annual consolidated and combined financial statements included in its Annual Report on Form 10-K for the period ended September 30, 2016, filed with the U.S. Securities and Exchange Commission ("SEC") on November 29, 2016.

On August 24, 2016, the Company announced that it had entered into a definitive agreement to sell its Nuclear Imaging business to IBA Molecular ("IBAM") for approximately $690.0 million before tax impacts, including up-front consideration of approximately $574.0 million, up to $77.0 million of contingent consideration and the assumption of certain liabilities. The Nuclear Imaging business was deemed to be held for sale. As a result, prior year balances have been recast to present the financial results of the Nuclear Imaging business as a discontinued operation. The sale was completed on January 27, 2017.

Fiscal Year

The Company historically reported its results based on a "52-53 week" year ending on the last Friday of September. On May 17, 2016, the Board of Directors of the Company approved a change in the Company’s fiscal year end to the last Friday in December from the last Friday in September. The change in fiscal year became effective for the Company’s 2017 fiscal year, which began on December 31, 2016 and will end on December 29, 2017. As a result of the change in fiscal year end, this document reflects the Company's Transition Report on Form 10-Q for the period from October 1, 2016 through December 30, 2016. Unless otherwise

indicated, the three months ended December 30, 2016 refers to the thirteen week period ended December 30, 2016 and the three months ended December 25, 2015 refers to the thirteen week period ended December 25, 2015.

2. Recently Issued Accounting Standards

The Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") 2017-04, "*Intangibles - Goodwill and Other: Simplifying the Test for Goodwill Impairment*" in January 2017. This update eliminates step 2 from the goodwill impairment test, and requires the goodwill impairment test to be performed by comparing the fair value of a reporting unit with its carrying amount. An impairment charge should be recognized for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. This guidance is effective for the Company in the first quarter of fiscal 2020. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company will assess the timing of adoption and impact of this guidance to future impairment considerations.

The FASB issued ASU 2017-01, "*Business Combinations (Topic 805): Clarifying the Definition of a Business*," in January 2017. This update provides a screen to determine whether or not a set of assets is a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set of assets is not a business. If the screen is not met, the amendments in this update (1) require that to be considered a business, a set of assets must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output and (2) remove the evaluation of whether a market participant could replace missing elements. This guidance is effective for the Company in the first quarter of fiscal 2018. Early adoption is permitted for transactions not previously reported in the Company's consolidated financial statements. The Company will assess the timing of adoption and impact of this guidance on further transactions.

The FASB issued ASU 2016-18, "*Statement of Cash Flows (Topic 230): Restricted Cash*," in November 2016. This update requires amounts deemed to be restricted cash and restricted cash equivalents to be classified in the cash and cash equivalent balances in the statement of cash flows. In addition, transfers between cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents are not part of operating, investing, and financing activities, and details of those transfers are not reported as cash flow activities in the statement of cash flows. This guidance is effective for the Company in the first quarter of fiscal 2018, with early adoption permitted. The Company is assessing the timing of adoption, but currently does not expect this standard to have a material impact to the statement of cash flows in future periods.

The Company's status of various ASUs are further described within the notes to the financial statements included within the Company's Annual Report filed on Form 10-K for the fiscal year ended September 30, 2016.

3. Discontinued Operations

Discontinued Operations

Nuclear Imaging: During the fourth quarter of fiscal 2016, the Company announced that it had entered into a definitive agreement to sell its Nuclear Imaging business to IBAM. The Nuclear Imaging business was deemed to be held for sale and the financial results of this business are presented as a discontinued operation. The sale was completed on January 27, 2017.

The following table summarizes the financial results of the Nuclear Imaging business for the three months ended December 30, 2016 and December 25, 2015 as presented in the consolidated statements of income:

	Three Months Ended	
Major line items constituting income from discontinued operations	**December 30, 2016**	**December 25, 2015**
Net sales	$ 99.4	$ 103.6
Cost of sales	44.7	62.8
Selling, general and administrative	16.4	19.2
Restructuring charges, net	—	2.2
Other	0.2	2.1
Income from discontinued operations	38.1	17.3
Income tax expense	15.3	5.2
Income from discontinued operations, net of income taxes	$ 22.8	$ 12.1

The income tax expense for the three months ended December 30, 2016 of $15.3 million was impacted by tax expense of $4.4 million associated with the rate difference between United Kingdom ("U.K.") and non-U.K. jurisdictions, $3.3 million of tax expense associated with accrued income tax liabilities and uncertain tax positions, and $0.1 million of tax expense associated with permanently nondeductible, nontaxable, and other items. The income tax expense for the three months ended December 25, 2015 of $5.2 million was impacted by $1.9 million of tax expense associated with the rate difference between U.K. and non-U.K. jurisdictions and $0.2 million of tax expense associated with permanently nondeductible, nontaxable, and other items. The three months ended December 30, 2016 reflects $15.8 million of non-U.K. current income tax expense and $0.5 million of non-U.K. deferred income tax benefit. The three months ended December 25, 2015 reflects $5.6 million of non-U.K. current income tax expense and $0.4 million of non-U.K. deferred income tax expense.

The following table summarizes the assets and liabilities of the Nuclear Imaging business that are classified as held for sale on the consolidated balance sheets as of December 30, 2016 and September 30, 2016:

	December 30, 2016	September 30, 2016
Carrying amounts of major classes of assets included as part of discontinued operations		
Accounts receivable	$ 49.6	$ 53.7
Inventories	20.0	19.0
Property, plant and equipment, net	188.7	189.0
Other current and non-current assets	52.6	47.1
Total assets classified as held for sale in the balance sheet	$ 310.9	$ 308.8
Carrying amounts of major classes of liabilities included as part of discontinued operations		
Accounts payable	$ 19.7	$ 17.7
Other current and non-current liabilities	100.6	103.1
Total liabilities classified as held for sale in the balance sheet	$ 120.3	$ 120.8

The following table summarizes significant cash and non-cash transactions of the Nuclear Imaging business that are included within the consolidated statements of cash flows for the respective periods:

	Three Months Ended	
	December 30, 2016	December 25, 2015
Depreciation	$ —	$ 6.6
Capital expenditures	2.0	1.9

All other notes to the consolidated financial statements that were impacted by this discontinued operation have been reclassified accordingly.

CMDS

On November 27, 2015, the Company completed the sale of the CMDS business to Guerbet S.A. ("Guerbet") for cash consideration of approximately $270.0 million, subject to net working capital adjustments.

Subsequent to the sale of the CMDS business, the Company has and will continue to supply certain products under a supply agreement with Guerbet.

The following table summarizes the financial results of the CMDS discontinued operations for the three months ended December 30, 2016 and December 25, 2015 as presented in the consolidated statements of income and comprehensive income:

	Three Months Ended	
Major line items constituting income from discontinued operations	**December 30, 2016**	**December 25, 2015**
Net sales	$ —	$ 59.2
Cost of sales	—	44.8
Selling, general and administrative expenses	—	18.2
Other	—	1.1
(Loss) from discontinued operations	—	(4.9)
Gain on disposal of discontinued operations	—	97.0
Income from discontinued operations, before income taxes	—	92.1
Income tax benefit	—	(2.7)
Income from discontinued operations net of tax	**$ —**	**$ 94.8**

The income tax benefit for the three months ended December 25, 2015 of $2.7 million was impacted by a $0.7 million benefit to adjust the fiscal 2015 accrual for taxes paid in connection with the $97.0 million gain on the disposition and a $2.0 million benefit related to the $4.9 million loss from discontinued operations.

The following table summarizes significant cash and non-cash transactions of the CMDS business that are included within the consolidated statements of cash flows for the respective periods:

	Three Months Ended	
	December 30, 2016	**December 25, 2015**
Depreciation	$ —	$ —
Amortization	—	—
Capital expenditures	—	1.6

All other notes to the consolidated financial statements that were impacted by this discontinued operation have been reclassified accordingly.

4. Acquisitions and License Agreements

The Company did not close any acquisitions during the three months ended December 30, 2016 or December 25, 2015. The Company closed acquisitions in the periods prior to and subsequent to the three months ended December 25, 2015 that may affect the comparability of the condensed consolidated statements of net income in this Transition Report on Form 10-Q. During the three months ended December 30, 2016 and December 25, 2015, the Company recognized $3.6 million and $16.2 million, respectively, of expense primarily associated with fair value adjustments of acquired inventory. The amount of acquisition-related costs included within operating income for the three months ended December 30, 2016 and December 25, 2015 were $0.1 million and $1.1 million, respectively.

The Company's acquisitions and license agreements are further described within the notes to the financial statements included within the Company's Annual Report filed on Form 10-K for the fiscal year ended September 30, 2016.

5. Restructuring and Related Charges

During fiscal 2013, the Company's Board of Directors approved a restructuring program in the amount of $100.0 million to $125.0 million ("the 2013 Mallinckrodt Program") that was planned to occur over a three-year period from the approval of the program, with an anticipated two-year cost recovery period. The 2013 Mallinckrodt Program is substantially complete.

In July 2016, the Company's Board of Directors approved a $100.0 million to $125.0 million restructuring program ("the 2016 Mallinckrodt Program"), designed to further improve its cost structure as the Company continues to transform its business. The 2016 Mallinckrodt Program is expected to include actions across both the Specialty Brands and Specialty Generics segments, as well as

within corporate functions. There is no specified time period associated with the 2016 Mallinckrodt Program. In addition to the 2016 Mallinckrodt Program, the Company takes certain restructuring actions to generate synergies from its acquisitions.

Net restructuring and related charges within continuing operations by segment are as follows:

	Three Months Ended	
	December 30, 2016	December 25, 2015
Specialty Brands	$ 2.6	$ 1.6
Specialty Generics	0.8	1.1
Corporate	1.9	1.5
Restructuring and related charges, net	5.3	4.2
Less: accelerated depreciation	(1.5)	(0.1)
Restructuring charges, net	$ 3.8	$ 4.1

Net restructuring and related charges by program within continuing operations are comprised of the following:

	Three Months Ended	
	December 30, 2016	December 25, 2015
2016 Mallinckrodt Program	$ 5.2	$ —
2013 Mallinckrodt Program	—	3.5
Acquisitions	0.1	0.7
Total	5.3	4.2
Less: non-cash charges, including accelerated share-based compensation expense	(1.5)	(0.1)
Total charges expected to be settled in cash	$ 3.8	$ 4.1

The following table summarizes cash activity for restructuring reserves, substantially all of which are related to employee severance and benefits:

	2016 Mallinckrodt Program	2013 Mallinckrodt Program	Acquisitions	Total
Balance at September 30, 2016	$ 6.2	$ 11.8	$ 0.5	$ 18.5
Charges	3.7	—	0.1	3.8
Cash payments	(0.4)	(6.7)	(0.4)	(7.5)
Balance at December 30, 2016	$ 9.5	$ 5.1	$ 0.2	$ 14.8

Net restructuring and related charges, including associated asset impairments, incurred cumulative-to-date related to the 2016 and 2013 Mallinckrodt Programs were as follows:

	2016 Mallinckrodt Program	2013 Mallinckrodt Program
Specialty Brands	$ 7.2	$ 18.8
Specialty Generics	1.3	18.3
Discontinued Operations (including Nuclear and CMDS)	—	69.9
Corporate	5.0	18.4
	$ 13.5	$ 125.4

Substantially all of the restructuring reserves were included in accrued and other current liabilities on the Company's unaudited condensed consolidated balance sheets.

6. Income Taxes

The Company recognized an income tax benefit of $121.7 million on a loss from continuing operations before income taxes of $298.5 million for the three months ended December 30, 2016 and an income tax benefit of $37.3 million on income from continuing operations before income taxes of $66.5 million for the three months ended December 25, 2015.This resulted in effective tax rates of 40.8% and negative 56.1% for the three months ended December 30, 2016 and December 25, 2015, respectively.

The effective tax rate for the three months ended December 30, 2016 was impacted by receiving $12.7 million of tax benefit associated with an adjustment to the Company's wholly owned partnership investment, $123.0 million of tax benefit associated with the rate difference between U.K. and non-U.K. jurisdictions, and $75.3 million of permanently non-deductible amounts associated with a goodwill impairment. The effective tax rate for the three months ended December 25, 2015 was impacted by $3.3 million of tax benefit associated with accrued income tax liabilities and uncertain tax positions, $3.6 million of tax benefit associated with U.S. tax credits, and $45.1 million of tax benefit associated with the rate difference between U.K. and non-U.K. jurisdictions.

The rate difference between U.K. and non-U.K jurisdictions increased from $45.1 million of tax benefit for the three months ended December 25, 2015 to an $123.0 million tax benefit for the three months ended December 30, 2016. This increase was predominately related to recent acquisitions, which resulted in more income in lower tax rate jurisdictions and less income in the higher tax rate U.S. jurisdiction relative to income in all jurisdictions. The change in the lower tax rate jurisdictions was primarily attributable to increased operating income. The change in the U.S. jurisdiction was primarily attributable to decreased operating income and the cost of financing recent acquisitions. The $77.9 million increase in the tax benefit included increases of $59.9 million of tax benefit attributed to changes in operating income and $18.0 million of tax benefit related to acquisition and other non-acquisition related items including the settlement with governmental authorities.

Non-current deferred tax liability decreased from $2,581.4 million at September 30, 2016 to $2,398.1 million at December 30, 2016, primarily due to $84.0 million of decreases associated with the payment of internal installment sale obligations, $51.6 million of decreases associated with net operating losses, $36.6 million of decreases related to the settlement with governmental authorities and $13.7 million of decreases associated with the amortization of intangibles partially offset by $2.6 million of increases related to normal operating activity.

At December 30, 2016, the Company had $1,074.7 million of net operating loss carryforwards in certain non-U.K. jurisdictions, of which $954.2 million have no expiration and the remaining $120.5 million will expire in future years through 2036. The Company had $89.6 million of U.K. net operating loss carryforwards at December 30, 2016, which have no expiration date.

The deferred tax asset valuation allowances of $1,398.3 million and $564.9 million at December 30, 2016 and September 30, 2016, respectively, relate principally to the uncertainty of the utilization of certain deferred tax assets, primarily non-U.K. net operating losses and intangible assets. The Company believes that it will generate sufficient future taxable income to realize the tax benefits related to the remaining net deferred tax assets.

The increase in non-U.K. net operating losses and valuation allowances are predominately related to statutory deductions associated with the impairment of the Generics operating segment and internal transactions.

During the three months ended December 30, 2016, the Company recognized an income tax expense of $15.3 million associated with the Nuclear Imaging business, as discussed in Note 3, in discontinued operations within the unaudited condensed consolidated statement of income.

The Company's unrecognized tax benefits, excluding interest, totaled $118.7 million at December 30, 2016 and $114.8 million at September 30, 2016. The net increase of $3.9 million primarily resulted from a net increase to current year positions of $5.0 million, and net decreases from prior period tax positions of $1.1 million. If favorably settled, $116.9 million of unrecognized tax benefits at December 30, 2016 would favorably impact the effective tax rate. The total amount of accrued interest related to these obligations was $7.1 million at December 30, 2016 and $7.2 million at September 30, 2016.

It is reasonably possible that within the next twelve months, as a result of the resolution of various U.K. and non-U.K. examinations, appeals and litigation, additions related to prior period tax positions and the expiration of various statutes of limitation, that the unrecognized tax benefits will decrease by up to $13.5 million and the amount of related interest and penalties will decrease by up to $4.9 million.

7. Earnings per Share

Basic earnings per share is computed by dividing net income by the number of weighted-average shares outstanding during the period. Diluted earnings per share is computed using the weighted-average shares outstanding and, if dilutive, potential ordinary shares outstanding during the period. Potential ordinary shares represent the incremental ordinary shares issuable for restricted share units and share option exercises. The Company calculates the dilutive effect of outstanding restricted share units and share options on earnings per share by application of the treasury stock method. In periods where losses are incurred, potential ordinary shares outstanding are excluded from the calculation of diluted earnings per share as they would be anti-dilutive.

The weighted-average number of shares outstanding used in the computations of basic and diluted earnings per share were as follows:

	Three Months Ended	
	December 30, 2016	December 25, 2015
Basic	105.7	115.4
Dilutive impact of restricted share units and share options	—	0.9
Diluted	105.7	116.3

The computation of diluted weighted-average shares outstanding for the three months ended December 30, 2016 and December 25, 2015 excludes approximately 2.4 million and 0.6 million shares of equity awards, respectively, because the effect would have been anti-dilutive.

8. Inventories

Inventories were comprised of the following at the end of each period:

	December 30, 2016	September 30, 2016
Raw materials and supplies	$ 72.6	$ 62.0
Work in process	178.4	188.9
Finished goods	99.7	84.7
	$ 350.7	$ 335.6

9. Property, Plant and Equipment

The gross carrying amount and accumulated depreciation of property, plant and equipment at the end of each period was as follows:

	December 30, 2016	September 30, 2016
Property, plant and equipment, gross	$ 1,679.4	$ 1,615.7
Less: accumulated depreciation	(797.9)	(771.7)
Property, plant and equipment, net	$ 881.5	$ 844.0

Depreciation expense for property, plant and equipment was $27.5 million and $25.7 million during the three months ended December 30, 2016 and December 25, 2015, respectively.

10. Goodwill and Intangible Assets

The gross carrying amount of goodwill by segment at the end of each period were as follows:

	December 30, 2016		September 30, 2016	
	Gross Carrying Amount	Accumulated Impairment	Gross Carrying Amount	Accumulated Impairment
Specialty Brands	$ 3,498.1	$ —	3,498.3	$ —
Specialty Generics	207.0	(207.0)	207.0	—
Total	$ 3,705.1	$ (207.0)	$ 3,705.3	$ —

As disclosed in the Annual Report on Form 10-K for the fiscal year ended September 30, 2016, the Company provided language that described that the Specialty Generics reporting unit had experienced customer consolidation and increased competition that have and are expected to result in further downward pressure to net sales and operating income in this reporting unit. During the three months ended December 30, 2016, the FDA approved new products that are expected to compete with the Company's Methylphenidate ER products and that one competitor launched their Methylphenidate ER products. Additional products expected to compete with the Company's Methylphenidate ER products may be launched during fiscal 2017. All of these products have a class AB rating compared with the class BX rating on the Company's Methylphenidate ER products. It is uncertain how these product approvals may impact the FDA's withdrawal proceedings associated with the Company's Methylphenidate ER products. The Company determined that these events represented a triggering event and the Company performed an assessment of the goodwill associated with the Specialty Generics reporting unit as of December 30, 2016.

The Company's projections in the Specialty Generics reporting unit include long-term net sales and operating income at lower than historical levels primarily attributable to customer consolidation and increased competition, including the competition effects on Methylphenidate ER. The Company utilized a WACC of 9.5% which reflects the Company's risk premium associated with the projected cash flows. These assumptions resulted in a fair value of the Specialty Generics reporting unit that was less than its net book value. The Company performed step two of the goodwill impairment test and recognized a $207.0 million goodwill impairment in the Specialty Generics segment.

The gross carrying amount and accumulated amortization of intangible assets at the end of each period were as follows:

	December 30, 2016		September 30, 2016	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Amortizable:				
Completed technology	$ 10,028.7	$ 1,617.1	$ 10,028.8	$ 1,446.2
Licenses	177.1	112.7	185.1	112.3
Customer relationships	27.6	8.4	28.6	8.0
Trademarks	82.1	10.9	82.2	10.0
Other	6.7	6.7	6.7	6.7
Total	$ 10,322.2	$ 1,755.8	$ 10,331.4	$ 1,583.2
Non-Amortizable:				
Trademarks	$ 35.0		$ 35.0	
In-process research and development	399.1		399.1	
Total	$ 434.1		$ 434.1	

Intangible asset amortization expense within continuing operations was $175.7 million and $173.4 million during the three months ended December 30, 2016 and December 25, 2015, respectively. The Company recorded a $7.3 million impairment of licenses associated with a product the Company elected to discontinue. The estimated aggregate amortization expense on intangible assets owned by the Company is expected to be as follows:

Fiscal 2017	$ 697.8
Fiscal 2018	691.3
Fiscal 2019	691.0
Fiscal 2020	690.8
Fiscal 2021	690.6

11. Debt

Debt was comprised of the following at the end of each period:

	December 30, 2016		September 30, 2016	
	Principal	Unamortized Discount and Debt Issuance Costs	Principal	Unamortized Discount and Debt Issuance Costs
Current maturities of long-term debt:				
Variable-rate receivable securitization	$ 250.0	$ 0.3	$ 235.0	$ 0.4
Term loan due March 2021	20.0	0.3	20.0	0.4
4.00% term loan due February 2022	1.0	—	1.1	—
Capital lease obligation and vendor financing agreements	0.8	—	1.0	—
Total current debt	271.8	0.6	257.1	0.8
Long-term debt:				
3.50% notes due April 2018	300.0	0.9	300.0	1.1
4.875% notes due April 2020	700.0	8.2	700.0	8.8
Term loan due March 2021	1,928.5	33.4	1,933.5	35.4
4.00% term loan due February 2022	5.5	—	6.0	—
9.50% debentures due May 2022	10.4	—	10.4	—
5.75% notes due August 2022	884.0	11.6	884.0	12.1
8.00% debentures due March 2023	4.4	—	4.4	—
4.75% notes due April 2023	600.0	6.1	600.0	6.4
5.625% notes due October 2023	738.0	11.4	740.0	11.8
5.50% notes due April 2025	695.0	10.2	700.0	10.6
Revolving credit facility	100.0	3.2	—	3.6
Capital lease obligation and vendor financing agreements	—	—	0.2	—
Total long-term debt	5,965.8	85.0	5,878.5	89.8
Total debt	$ 6,237.6	$ 85.6	$ 6,135.6	$ 90.6

The Company's debt instruments are further described within the notes to the financial statements included within the Company's Annual Report filed on Form 10-K for the fiscal year ended September 30, 2016.

As of December 30, 2016, the applicable interest rate on outstanding borrowings under the Company's revolving credit facility was approximately 3.25%, and there were $100.0 million in outstanding borrowings. As of December 30, 2016, the applicable interest rate on outstanding borrowings under the variable-rate receivable securitization was 1.57%, and outstanding borrowings totaled $250.0 million. At December 30, 2016, the weighted-average interest rate for the term loan due March 2021 was 3.59%, and outstanding borrowings totaled $1,948.5 million.

As of December 30, 2016, the Company continues to be in full compliance with the provisions and covenants associated with its debt agreements.

12. Retirement Plans

The net periodic benefit cost for the Company's defined benefit pension plans was as follows:

	Three Months Ended	
	December 30, 2016	December 25, 2015
Service cost	$ 0.2	$ 0.4
Interest cost	0.5	3.5
Expected return on plan assets	(0.6)	(4.2)
Amortization of net actuarial loss	1.0	2.6
Plan settlements	45.0	—
Net periodic benefit cost	$ 46.1	$ 2.3

The net periodic benefit credit for the Company's postretirement benefit plans was approximately zero for the three months ended both December 30, 2016 and December 25, 2015.

Net periodic benefit cost for the Company's defined benefit pension plans and postretirement benefit plans was included within cost of sales; research and development; and selling, general and administrative ("SG&A") expenses on the unaudited condensed consolidated statements of income.

Pension Plan Termination

On March 31, 2016, the Company terminated six of its previously frozen U.S. pension plans. During the three months ended December 30, 2016, the Company made lump sum distributions of $125.5 million from the terminated pension plans, based upon employee elections. These disbursements resulted in a $45.0 million charge, included within SG&A expenses, associated with the recognition of previously deferred pension related losses upon lump sum distribution to employees under our pension plan termination. The Company continues to pursue settlement of remaining obligations under these plans, the ultimate settlement obligation and future settlement charges will depend upon the nature of participant settlements and the prevailing market conditions. Final settlement of the remaining pension obligations under these plans is anticipated in the first half of calendar 2017.

13. Accumulated Other Comprehensive Income

The following summarizes the change in accumulated other comprehensive income for the three months ended December 30, 2016 and December 25, 2015:

	Currency Translation	Unrecognized Gain (Loss) on Derivatives	Unrecognized Gain (Loss) on Benefit Plans	Accumulated Other Comprehensive Income
Balance at September 30, 2016	$ 1.6	$ (5.9)	$ (81.3)	$ (85.6)
Other comprehensive (loss) income before reclassifications	(21.1)	—	5.3	(15.8)
Amounts reclassified from accumulated other comprehensive income	—	0.2	28.7	28.9
Net current period other comprehensive income (loss)	(21.1)	0.2	34.0	13.1
Balance at December 30, 2016	$ (19.5)	$ (5.7)	$ (47.3)	$ (72.5)

	Currency Translation	Unrecognized Gain (Loss) on Derivatives	Unrecognized Gain (Loss) on Benefit Plans	Accumulated Other Comprehensive Income
Balance at September 25, 2015	$ 60.2	$ (6.4)	$ (52.9)	$ 0.9
Other comprehensive income before reclassifications	(9.4)	—	—	(9.4)
Amounts reclassified from accumulated other comprehensive income	(58.7)	0.1	1.8	(56.8)
Net current period other comprehensive income (loss)	(68.1)	0.1	1.8	(66.2)
Balance at December 25, 2015	$ (7.9)	$ (6.3)	$ (51.1)	$ (65.3)

The following summarizes reclassifications out of accumulated other comprehensive income for the three months ended December 30, 2016 and December 25, 2015:

	Amount Reclassified from Accumulated Other Comprehensive Income		
	Three Months Ended December 30, 2016	Three Months Ended December 25, 2015	Line Item in the Unaudited Condensed Consolidated Statement of Income
Amortization of unrealized loss on derivatives	$ 0.2	$ 0.1	Interest expense
Income tax provision	—	—	Income tax benefit
Net of income taxes	0.2	0.1	
Amortization of pension and post-retirement benefit plans:			
Net actuarial loss	1.0	2.6	(1)
Prior service credit	(0.6)	(0.6)	(1)
Disposal of discontinued operations	—	0.8	Income from discontinued operations, net of income taxes
Plan settlements	45.0	—	(1) Selling, general and administrative expenses
Total before tax	45.4	2.8	
Income tax provision	(16.7)	(1.0)	Income tax benefit
Net of income taxes	28.7	1.8	
Currency translation	—	(58.7)	Income from discontinued operations, net of income taxes
Total reclassifications for the period	$ 28.9	$ (56.8)	

(1) These accumulated other comprehensive income components are included in the computation of net periodic benefit cost. See Note 12 for additional details.

14. Equity

Share Repurchases

On November 19, 2015, the Company's Board of Directors authorized a $500.0 million share repurchase program (the “November 2015 Program”), which was completed in the three months ended December 30, 2016. The November 2015 Program commenced after the $300.0 million share repurchase program authorized by the Company's Board of Directors on January 23, 2015 (the “January 2015 Program”) was completed in the three month period ended December 25, 2015. On March 16, 2016, the Company's Board of Directors authorized an additional $350.0 million share repurchase program (the “March 2016 Program”) which commenced upon the completion of the November 2015 Program. The March 2016 Program has no time limit or expiration date, and the Company currently expects to fully utilize the program.

	March 2016 Repurchase Program		November 2015 Repurchase Program		January 2015 Repurchase Program	
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount
Authorized repurchase amount		$ 350.0		$ 500.0		$ 300.0
Repurchases:						
Fiscal 2015	—	—	—	—	823,592	75.0
Fiscal 2016	—	—	6,510,824	425.6	3,199,279	225.0
Transition Period 2016	1,501,676	84.0	1,063,337	74.4	—	—
Remaining amount available		$ 266.0		$ —		$ —

The Company also repurchases shares from employees in order to satisfy employee tax withholding requirements in connection with the vesting of restricted shares and share option exercises.

15. Guarantees

In disposing of assets or businesses, the Company has historically provided representations, warranties and indemnities to cover various risks and liabilities, including unknown damage to the assets, environmental risks involved in the sale of real estate, liability to investigate and remediate environmental contamination at waste disposal sites and manufacturing facilities, and unidentified tax liabilities related to periods prior to disposition. The Company assesses the probability of potential liabilities related to such representations, warranties and indemnities and adjusts potential liabilities as a result of changes in facts and circumstances. The Company believes, given the information currently available, that their ultimate resolutions will not have a material adverse effect on its financial condition, results of operations and cash flows.

In connection with the sale of Mallinckrodt Baker in fiscal 2010, the Company agreed to indemnify the purchaser with respect to various matters, including certain environmental, health, safety, tax and other matters. The indemnification obligations relating to certain environmental, health and safety matters have a term of 17 years from the sale, while some of the other indemnification obligations have an indefinite term. The amount of the liability relating to all of these indemnification obligations included in other liabilities on the Company's unaudited condensed consolidated balance sheets as of December 30, 2016 and September 30, 2016 was $15.1 million and $15.7 million, respectively, of which $12.4 million and $12.9 million, respectively, related to environmental, health and safety matters. The value of the environmental, health and safety indemnity was measured based on the probability-weighted present value of the costs expected to be incurred to address environmental, health and safety claims made under the indemnity. The aggregate fair value of these indemnification obligations did not differ significantly from their aggregate carrying value at December 30, 2016 and September 30, 2016. As of December 30, 2016, the maximum future payments the Company could be required to make under these indemnification obligations were $71.0 million. The Company was required to pay $30.0 million into an escrow account as collateral to the purchaser, of which $19.0 million remained in other assets on the unaudited condensed consolidated balance sheets at both December 30, 2016 and September 30, 2016.

The Company has recorded liabilities for known indemnification obligations included as part of environmental liabilities, which are discussed in Note 16.

In addition, the Company is also liable for product performance; however, the Company believes, given the information currently available, that their ultimate resolutions will not have a material adverse effect on its financial condition, results of operations and cash flows.

The Company is required to provide the U.S. Nuclear Regulatory Commission financial assurance demonstrating its ability to fund the decommissioning of its Maryland Heights, Missouri radiopharmaceuticals production facility upon closure, though the Company does not intend to close this facility. The Company has provided this financial assurance in the form of surety bonds totaling $30.2 million. As of December 30, 2016, the Company had various other letters of credit, guarantees and surety bonds totaling $28.4 million.

In addition, the separation and distribution agreement entered into with Covidien plc ("Covidien"), as part of the Company's legal separation from Covidien, provides for cross-indemnities principally designed to place financial responsibility of the obligations and liabilities of the Company's business with the Company and financial responsibility for the obligations and liabilities of Covidien's remaining business with Covidien, among other indemnities.

16. Commitments and Contingencies

The Company is subject to various legal proceedings and claims, including patent infringement claims, product liability matters, environmental matters, employment disputes, contractual disputes and other commercial disputes, including those described below. The Company believes that these legal proceedings and claims likely will be resolved over an extended period of time. Although it is not feasible to predict the outcome of these matters, the Company believes, unless indicated below, given the information currently available, that their ultimate resolutions will not have a material adverse effect on its financial condition, results of operations and cash flows.

Governmental Proceedings

In January 2017, the Company received a subpoena from the SEC for documents related to the Company’s public statements, filings and other disclosures regarding Acthar sales, profits, revenue, promotion and pricing.

In December 2016, the Company received a subpoena from the United States Attorney’s Office ("USAO") for the District of Massachusetts for documents related to the Company’s provision of financial and other support to patients, including through charitable foundations, and related matters.

In November 2014, the Company received a Civil Investigative Demand ("CID") from the Civil Medicaid Fraud Division of the Texas Attorney General's Office. According to the CID, the Attorney General's office is investigating the possibility of false reporting of information by the Company regarding the prices of certain of its drugs used by Texas Medicaid to establish reimbursement rates for pharmacies that dispensed the Company's drugs to Texas Medicaid recipients.

Mallinckrodt Inc. v. U.S. Food and Drug Administration and United States of America. The Company filed a Complaint for Declaratory and Injunctive Relief ("the Complaint") in the U.S. District Court for the District of Maryland Greenbelt Division against the FDA and the United States of America in November 2014 for judicial review of what the Company believes is the FDA's inappropriate and unlawful reclassification of the Company's Methylphenidate HCl Extended-Release tablets USP (CII) ("Methylphenidate ER") in the Orange Book: Approved Drug Products with Therapeutic Equivalence ("Orange Book") on November 13, 2014. In its Complaint, the Company asked the court to: issue an injunction to (a) set aside the FDA's reclassification of the Company's Methylphenidate ER products from freely substitutable at the pharmacy level (class AB) to presumed to be therapeutically inequivalent (class BX) in the Orange Book and (b) prohibit the FDA from reclassifying the Company's Methylphenidate ER products in the future without following applicable legal requirements; and issue a declaratory judgment that the FDA's action reclassifying the Company's Methylphenidate ER products in the Orange Book is unlawful. The Company concurrently filed a motion with the same court requesting an expedited hearing to issue a temporary restraining order ("TRO") directing the FDA to reinstate the Orange Book AB rating for the Company's Methylphenidate ER products on a temporary basis. The court denied the Company's motion for a TRO. In December 2014, the FDA filed a motion to dismiss the Complaint with the district court. The Company filed its opposition to the motion to dismiss in January 2015, and concurrently filed a motion for summary judgment. In July 2015, the court granted the FDA's motion to dismiss with respect to three of the five counts in the Complaint and granted summary judgment in favor of the FDA with respect to the two remaining counts. The Company appealed the court's decision to the U.S. Court of Appeals for the Fourth Circuit. On October 18, 2016, the FDA initiated proceedings, proposing to withdraw approval of Mallinckrodt's Abbreviated New Drug Application ("ANDA") for Methylphenidate ER. On October 21, 2016, the United States Court of Appeals for the Fourth Circuit issued an Order removing the Company's pending litigation with the FDA from the Court's oral argument calendar and placing that litigation in abeyance pending the outcome of the withdrawal proceedings. The Company concurrently submitted to the FDA requests for a hearing in the withdrawal proceeding and for a 90-day extension of the deadline for submitting documentation supporting the necessity of a hearing. The FDA has granted the Company's extension request, with a new deadline of March 20, 2017, and the Company is preparing the supporting documentation for the March submission. The Company plans to vigorously set forth its position in the withdrawal proceedings.

In March 2014, the USAO for the Eastern District of Pennsylvania requested the production of documents related to an investigation of the U.S. promotion of Therakos' immunotherapy drug/device system UVADEX/UVAR XTS and UVADEX/CELLEX (collectively, the "Therakos System"), for indications not approved by the FDA, including treatment of patients with graft versus host disease ("GvHD") and solid organ transplant patients, including pediatric patients. The investigation also includes Therakos' efforts to secure FDA approval for additional uses of, and alleged quality issues relating to, UVADEX/UVAR. In August 2015, the USAO for the Eastern District of Pennsylvania sent Therakos a subsequent request for documents related to the investigation and has since made certain related requests. We are in the process of responding to those requests.

In June 2014, Questcor received a subpoena and CID from the FTC seeking documentary materials and information regarding the FTC's investigation into whether Questcor's acquisition of certain rights to develop, market, manufacture, distribute, sell and commercialize MNK-1141 (the product formerly described as Synacthen Depot®) from Novartis AG and Novartis Pharma AG (collectively, "Novartis") violates antitrust laws. Subsequently, California, Maryland, Texas, Washington, New York and Alaska (collectively, "the Investigating States") commenced similar investigations focused on whether the transaction violates state antitrust laws. On January 17, 2017, the FTC, all Investigating States (except California) ("the Settling States") and the Company entered into an agreement to resolve this matter for a one-time cash payment of $102.0 million, which is included within SG&A, and an agreement to license MNK-1141 to a third party designated by the FTC for possible development in Infantile Spasms (IS) and Nephrotic Syndrome (NS) in the U.S. To facilitate that settlement, a complaint was filed on January 18, 2017, in the U.S. District Court for the District of Columbia. The settlement was approved by the court on January 30, 2017.

In September 2012, Questcor received a subpoena from the USAO for the Eastern District of Pennsylvania for information relating to its promotional practices related to Acthar. Questcor has also been informed by the USAO for the Eastern District of Pennsylvania that the USAO for the Southern District of New York and the SEC are participating in the investigation to review Questcor's promotional practices and related matters related to Acthar. On March 9, 2015, the Company received a "No Action" letter from the SEC regarding its review of the Company's promotional practices related to Acthar.

In November 2011 and October 2012, the Company received subpoenas from the U.S. Drug Enforcement Administration requesting production of documents relating to its suspicious order monitoring program for controlled substances. The USAO for the Eastern District of Michigan is investigating the possibility that the Company failed to report suspicious orders of controlled substances during the period 2006-2011 in violation of the Controlled Substances Act and its related regulations. The USAO for the Northern District of New York and Office of Chief Counsel for the U.S. Drug Enforcement Administration are investigating the possibility that the Company failed to maintain appropriate records and security measures with respect to manufacturing of certain controlled substances at its Hobart facility during the period 2012-2013. The Company believes, given the information currently

available, that the ultimate resolution, after taking into account amounts already accrued, will not have a material adverse effect on its financial condition, results of operations and cash flows.

We have responded to or are in the process of responding to each of the subpoenas and the CIDs and we intend to cooperate fully in each such investigation.

Patent/Antitrust Litigation

Inomax Patent Litigation: Praxair Distribution, Inc. and Praxair, Inc. (collectively "Praxair"). In February 2015, INO Therapeutics LLC and Ikaria, Inc., subsidiaries of the Company, filed suit in the U.S. District Court for the District of Delaware against Praxair following receipt of a January 2015 notice from Praxair concerning its submission of an ANDA containing a Paragraph IV patent certification with the FDA for a generic version of Inomax. In July 2016, the Company filed a second suit against Praxair in the U.S. District Court for the District of Delaware following receipt of a Paragraph IV notice concerning three additional patents recently added to the FDA Orange Book that was submitted by Praxair regarding its ANDA for a generic version of Inomax. The infringement claims in the second suit have been added to the original suit. In September 2016, the Company filed a third suit against Praxair in the U.S. District Court for the District of Delaware following receipt of a Paragraph IV notice concerning a fourth patent recently added to the FDA Orange Book that was submitted by Praxair regarding its ANDA for a generic version of Inomax.

The Company intends to vigorously enforce its intellectual property rights relating to Inomax in both the Inter Partes Review ("IPR") and Praxair litigation proceedings to prevent the marketing of infringing generic products prior to the expiration of the patents covering Inomax. An adverse outcome in either the IPRs or the Praxair litigation ultimately could result in the launch of a generic version of Inomax before the expiration of the last of the listed patents on February 19, 2034 (August 19, 2034 including pediatric exclusivity), which could adversely affect the Company's ability to successfully maximize the value of Inomax and have an adverse effect on its financial condition, results of operations and cash flows.

Inomax Patents: IPR Proceedings. In February 2015 and March 2015, the USPTO issued Notices of Filing Dates Accorded to Petitions for IPR petitions filed by Praxair Distribution, Inc. concerning ten patents covering Inomax (i.e., five patents expiring in 2029 and five patents expiring in 2031).

In July 2015, the USPTO Patent Trial and Appeal Board ("PTAB") issued rulings denying the institution of four of the five IPR petitions challenging the five patents expiring in 2029. The PTAB also issued a ruling in July 2015 that instituted the IPR proceeding in the fifth of this group of patents and the PTAB ruled in July 2016 that one claim of this patent survived review and is valid while the remaining claims were unpatentable. The Company believes the valid claim describes and encompasses the manner in which Inomax is distributed in conjunction with its approved labeling and that Praxair infringes that claim. Praxair filed an appeal and the Company filed a cross-appeal of this decision to the Court of Appeals for the Federal Circuit. In March 2016, Praxair Distribution, Inc. submitted additional IPR petitions for the five patents expiring in 2029. The PTAB issued non-appealable rulings in August and September 2016 denying institution of all five of these additional IPR petitions.

In September 2015, the USPTO PTAB issued rulings that instituted the IPR proceedings in each of the second set of five patents that expire in 2031. In September 2016, the PTAB ruled that all claims in the five patents expiring in 2031 are patentable.

'222 and '218 Patent Litigation: Agila Specialties Private Limited, Inc. (now Mylan Laboratories Ltd.) and Agila Specialties Inc. (a Mylan Inc. Company), (collectively "Agila"). In December 2014, Cadence and Mallinckrodt IP, subsidiaries of the Company, and Pharmatop, the owner of the two U.S. patents licensed exclusively by the Company, filed suit in the U.S. District Court for the District of Delaware against Agila alleging that Agila infringed U.S. Patent Nos. 6,028,222 ("the '222 patent") and 6,992,218 ("the '218 patent") following receipt of a November 2014 notice from Agila concerning its submission of a NDA containing a Paragraph IV patent certification with the FDA for a competing version of Ofirmev. Separately, on December 1, 2016 Mallinckrodt IP filed suit in the U.S. District Court for the District of Delaware against Agila alleging that Agila infringed the '012 patent. On December 31, 2016, the parties entered into settlement agreements on both suits under which Agila was granted the non-exclusive right to market a competing intravenous acetaminophen product in the U.S. under its NDA after December 6, 2020, or earlier under certain circumstances.

The Company has successfully asserted the '222 and '218 patents and maintained their validity in both litigation and proceedings at the U.S. Patent and Trademark Office ("USPTO"). The Company will continue to vigorously enforce its intellectual property rights relating to Ofirmev to prevent the marketing of infringing generic or competing products prior to December 6, 2020, which, if unsuccessful, could adversely affect the Company's ability to successfully maximize the value of Ofirmev and have an adverse effect on its financial condition, results of operations and cash flows.

'222 and '218 Patent Litigation: InnoPharma Licensing LLC and InnoPharma, Inc. In September 2014, Cadence and Mallinckrodt IP, subsidiaries of the Company, and Pharmatop, the owner of the two U.S. patents licensed exclusively by the Company, filed suit in the U.S. District Court for the District of Delaware against InnoPharma Licensing LLC and InnoPharma, Inc. (both are subsidiaries of Pfizer and collectively "InnoPharma") alleging that InnoPharma infringed the '222 and the '218 patents following receipt of an August 2014 notice from InnoPharma concerning its submission of a New Drug Application ("NDA"), containing a

Paragraph IV patent certification with the FDA for a competing version of Ofirmev. Separately, on December 1, 2016 Mallinckrodt IP filed suit in the U.S. District Court for the District of Delaware against InnoPharma alleging that InnoPharma infringed U.S. Patent No. 9,399,012 ("the '012 patent").

Tyco Healthcare Group LP, et al. v. Mutual Pharmaceutical Company, Inc. In March 2007, the Company filed a patent infringement suit in the U.S. District Court for the District of New Jersey against Mutual Pharmaceutical Co., Inc., et al. (collectively, "Mutual") after Mutual submitted an ANDA to the FDA seeking to sell a generic version of the Company's 7.5 mg RESTORIL™ sleep aid product. Mutual also filed antitrust and unfair competition counterclaims. The patents at issue have since expired or been found invalid. The trial court issued an opinion and order granting the Company's motion for summary judgment regarding Mutual's antitrust and unfair competition counterclaims. Mutual appealed this decision to the U.S. Court of Appeals for the Federal Circuit and the Federal Circuit issued a split decision, affirming the trial court in part and remanding to the trial court certain counterclaims for further proceedings. The Company filed a motion for summary judgment with the U.S. District Court regarding the remanded issues. In May 2015, the trial court issued an opinion granting-in-part and denying-in-part the Company's motion for summary judgment.

Commercial and Securities Litigation

Putative Class Action Securities Litigation. On January 23, 2017, a putative class action lawsuit was filed against the Company and Chief Executive Officer ("CEO") Mark Trudeau in the U.S. District Court for the District of Columbia, captioned *Patricia A. Shenk v. Mallinckrodt plc, et al*., No. 17-cv-00145-EGS. The complaint purports to be brought on behalf of all persons who purchased Mallinckrodt's publicly traded securities on a domestic exchange between November 25, 2014 and January 18, 2017. The lawsuit generally alleges that the Company made false or misleading statements related to Acthar and Synacthen to artificially inflate the price of the Company's stock. In particular, the complaint alleges a failure by the Company to provide accurate disclosures concerning the long-term sustainability of Acthar revenues, and the exposure of Acthar to Medicare and Medicaid reimbursement rates. On January 26, 2017, a second putative class action lawsuit, captioned *Jyotindra Patel v. Mallinckrodt plc, et al.*, No. 1:17-cv-00171 was filed against the same defendants named in the *Shenk* lawsuit in the U.S. District Court for the District of Columbia. The *Patel* complaint purports to be brought on behalf of shareholders during the same period of time as that set forth in the *Shenk* lawsuit and asserts claims similar to those set forth in the *Shenk* lawsuit.

Retrophin Litigation. In January 2014, Retrophin, Inc. ("Retrophin") filed a lawsuit against Questcor in the U.S. District Court for the Central District of California, alleging a variety of federal and state antitrust violations based on Questcor's acquisition from Novartis of certain rights to develop, market, manufacture, distribute, sell and commercialize Synacthen. In June 2015, the parties entered into a binding settlement agreement, under the terms of which Retrophin agreed to dismiss the litigation with prejudice and Questcor agreed to make a one-time cash payment to Retrophin in the amount of $15.5 million.

Putative Class Action Securities Litigation. In September 2012, a putative class action lawsuit was filed against Questcor and certain of its officers and directors in the U.S. District Court for the Central District of California, captioned *John K. Norton v. Questcor Pharmaceuticals, et al.*, No. SACvl2-1623 DMG (FMOx). The complaint purported to be brought on behalf of shareholders who purchased Questcor common stock between April 26, 2011 and September 21, 2012. The complaint generally alleged that Questcor and certain of its officers and directors engaged in various acts to artificially inflate the price of Questcor stock and enable insiders to profit through stock sales. The complaint asserted that Questcor and certain of its officers and directors violated sections l0(b) and/or 20(a) of the Securities Exchange Act of 1934, as amended ("the Exchange Act"), by making allegedly false and/or misleading statements concerning the clinical evidence to support the use of Acthar for indications other than infantile spasms, the promotion of the sale and use of Acthar in the treatment of multiple sclerosis and nephrotic syndrome, reimbursement for Acthar from third-party insurers, and Questcor's outlook and potential market growth for Acthar. The complaint sought damages in an unspecified amount and equitable relief against the defendants. This lawsuit was consolidated with four subsequently-filed actions asserting similar claims under the caption: *In re Questcor Securities Litigation*, No. CV 12-01623 DMG (FMOx). In October 2013, the District Court granted in part and denied in part Questcor's motion to dismiss the consolidated amended complaint. In October 2013, Questcor filed an answer to the consolidated amended complaint and fact discovery was concluded in January 2015. In April 2015, the parties executed a long-form settlement agreement, under the terms of which Questcor agreed to pay $38.0 million to resolve the plaintiff's claims, inclusive of all fees and costs. Questcor and the individual defendants maintain that the plaintiffs' claims are without merit, and entered into the settlement to eliminate the uncertainties, burden and expense of further protracted litigation. During fiscal 2015, the Company established a $38.0 million reserve for this settlement, which was subsequently paid to a settlement fund. The court issued its final approval of the settlement on September 18, 2015.

Glenridge Litigation. In June 2011, Glenridge Pharmaceuticals, LLC ("Glenridge"), filed a lawsuit against Questcor in the Superior Court of California, Santa Clara County, alleging that Questcor had underpaid royalties to Glenridge under a royalty agreement related to net sales of Acthar. In August 2012, Questcor filed a separate lawsuit against the three principals of Glenridge, as well as Glenridge, challenging the enforceability of the royalty agreement. In August 2013, the lawsuits were consolidated into one case in the Superior Court of California, Santa Clara County. In October 2014, the parties entered into a binding term sheet settling the lawsuit. Under the terms of the settlement, the royalty rate payable by Questcor was reduced, royalties were capped instead of being payable for so long as Acthar was sold and Questcor agreed to pay Glenridge a reduced amount in satisfaction of royalties Questcor

had previously accrued but not paid during the course of the lawsuit. In February 2015, the settlement agreement was finalized, with terms consistent with the October 2014 term sheet.

Pricing Litigation

State of Utah v. Apotex Corp., et al. The Company, along with several other pharmaceutical companies, was a defendant in this matter which was filed in May 2008, in the Third Judicial Circuit of Salt Lake County, Utah. The State of Utah alleges, generally, that the defendants reported false pricing information in connection with certain drugs that are reimbursable under Utah Medicaid, resulting in overpayment by Utah Medicaid for those drugs, and is seeking monetary damages and attorneys' fees. The Company believes that it has meritorious defenses to these claims and vigorously defended against them. In December 2015, the parties entered into a binding settlement agreement, under the terms of which the State of Utah agreed to dismiss the litigation with prejudice and the Company agreed to make a one-time cash payment to the State of Utah within the reserve established for this matter.

Environmental Remediation and Litigation Proceedings

The Company is involved in various stages of investigation and cleanup related to environmental remediation matters at a number of sites, including those described below. The ultimate cost of site cleanup and timing of future cash outlays is difficult to predict, given the uncertainties regarding the extent of the required cleanup, the interpretation of applicable laws and regulations and alternative cleanup methods. The Company concluded that, as of December 30, 2016, it was probable that it would incur remedial costs in the range of $38.9 million to $121.4 million. The Company also concluded that, as of December 30, 2016, the best estimate within this range was $76.0 million, of which $3.0 million was included in accrued and other current liabilities and the remainder was included in environmental liabilities on the unaudited condensed consolidated balance sheet at December 30, 2016. While it is not possible at this time to determine with certainty the ultimate outcome of these matters, the Company believes, given the information currently available, that the final resolution of all known claims, after taking into account amounts already accrued, will not have a material adverse effect on its financial condition, results of operations and cash flows.

Coldwater Creek, Saint Louis County, Missouri. The Company is named as a defendant in numerous tort complaints with numerous plaintiffs pending in the U.S. District Court for the Eastern District of Missouri that were filed in or after February 2012. These cases allege personal injury for alleged exposure to radiological substances, including in Coldwater Creek in Missouri, and in the air. Plaintiffs allegedly lived and/or worked in various locations in Saint Louis County, Missouri near Coldwater Creek. Radiological residues which may have been present in the creek have previously been remediated by the U.S. Army Corps of Engineers ("USACE"). The USACE continues to study and remediate the creek and surrounding areas. The Company believes that it has meritorious defenses to these complaints and is vigorously defending against them. The Company is unable to estimate a range of reasonably possible losses for the following reasons: (i) the proceedings are in intermediate stages; (ii) the Company has not received and reviewed complete information regarding the plaintiffs and their medical conditions; and (iii) there are significant factual and scientific issues to be resolved. An initial group of bellwether plaintiffs have been selected by the court and discovery is ongoing. While it is not possible at this time to determine with certainty the ultimate outcome of this case, the Company believes, given the information currently available, that the final resolution of all known claims, after taking into account amounts already accrued, will not have a material adverse effect on its financial condition, results of operations and cash flows.

Lower Passaic River, New Jersey. The Company and approximately 70 other companies originally comprised the Lower Passaic Cooperating Parties Group ("the CPG") and are parties to a May 2007 Administrative Order on Consent ("AOC") with the Environmental Protection Agency ("EPA") to perform a RI/FS of the 17-mile stretch known as the Lower Passaic River Study Area ("the River"). The Company's potential liability stems from former operations at Lodi and Belleville, New Jersey. In June 2007, the EPA issued a draft Focused Feasibility Study ("FFS") that considered interim remedial options for the lower 8-miles of the river, in addition to a "no action" option. As an interim step related to the 2007 AOC, on June 18, 2012 the CPG voluntarily entered into an AOC with the EPA for remediation actions focused solely at mile 10.9 of the River. The Company's estimated costs related to the RI/FS and focused remediation at mile 10.9, based on interim allocations, are immaterial and have been accrued.

In April 2014, the EPA issued its revised FFS, with remedial alternatives to address cleanup of the lower 8-mile stretch of the River, which also included a "no action" option. The EPA estimated the cost for the remediation alternatives ranged from $365.0 million to $3.2 billion. The EPA's preferred approach would involve bank-to-bank dredging of the lower 8-mile stretch of the River and installing an engineered cap at a discounted, estimated cost of $1.7 billion. Based on the issuance of the EPA's revised FFS, the Company recorded a $23.1 million accrual in the second quarter of fiscal 2014 representing the Company's estimate of its allocable share of the joint and several remediation liability resulting from this matter.

In April 2015, the CPG presented a draft of the RI/FS of the River to the EPA. The CPG's RI/FS included alternatives that ranged from "no action," targeted remediation of the entire 17-mile stretch of the River to remedial actions consistent with the EPA's preferred approach for the lower 8-mile stretch of the River and also included remediation alternatives for the upper 9-mile stretch of the River. The discounted cost estimates for the CPG remediation alternatives ranged from $483.4 million to $2.7 billion. The Company

recorded an additional charge of $13.3 million in the second quarter of fiscal 2015 based on the Company's estimate of its allocable share of the joint and several remediation liability resulting from this matter.

On March 4, 2016, the EPA issued the Record of Decision ("ROD") for the lower 8 miles of the River. The EPA's selected remedy for this stretch of the River was a slight modification of the preferred approach it identified in the revised FFS issued in April 2014. The new discounted, estimated cost is $1.38 billion. By letter dated March 31, 2016, EPA notified the Company, and approximately 98 other parties, of the Company's potential liability for the lower 8 miles of the River. The letter also announced the EPA's intent to seek to determine whether one company, Occidental Chemicals Corporation ("OCC"), will voluntarily enter into an agreement to perform the remedial design for the remedy selected in the ROD. The letter states that, after execution of such an agreement, EPA plans to begin negotiation of an agreement under which OCC and the other major PRPs would implement and/or pay for the EPA's selected remedy for the lower 8 miles of the River. Finally, the letter announced EPA's intent to provide a separate notice to unspecified parties of the opportunity to discuss a cash out settlement for the lower 8 miles of the River at a later date. On October 5, 2016, EPA announced that OCC had entered into an agreement to develop the remedial design.

Despite the issuance of the revised FFS and ROD by the EPA, and the RI/FS by the CPG, there are many uncertainties associated with the final agreed-upon remediation and the Company's allocable share of the remediation. As of November 20, 2015, the Company withdrew from the CPG, but remains liable for its obligations under the two above-referenced AOCs, as well as potential future liabilities. Given those uncertainties, the amounts accrued may not be indicative of the amounts for which the Company may be ultimately responsible and will be refined as the remediation progresses.

Mallinckrodt Veterinary, Inc., Millsboro, Delaware. The Company previously operated a plant in Millsboro, Delaware ("the Millsboro Site") that manufactured various animal healthcare products. In 2005, the Delaware Department of Natural Resources and Environmental Control found trichloroethylene ("TCE") in the Millsboro public water supply at levels that exceeded the federal drinking water standards. Further investigation to identify the TCE plume in the ground water indicated that the plume has extended to property owned by a third party near the Millsboro Site. The Company, and another former owner, have assumed responsibility for the Millsboro Site cleanup under the Alternative Superfund Program administered by the EPA. The Company and another PRP have entered into two AOCs with the EPA to perform investigations to abate, mitigate or eliminate the release or threat of release of hazardous substances at the Millsboro Site and to conduct an Engineering Evaluation/Cost Analysis ("EE/CA") to characterize the nature and extent of the contamination. The Company, along with the other party, continues to conduct the studies and prepare remediation plans in accordance with the AOCs. In January 2017, the EPA issued its Action Memorandum regarding the EE/CA. The parties are negotiating a third AOC to implement the removal action. While it is not possible at this time to determine with certainty the ultimate outcome of this matter, the Company believes, given the information currently available, that the ultimate resolution of all known claims, after taking into account amounts already accrued, will not have a material adverse effect on its financial condition, results of operations and cash flows.

Crab Orchard National Wildlife Refuge Superfund Site, near Marion, Illinois. The Company is a successor in interest to International Minerals and Chemicals Corporation ("IMC"). Between 1967 and 1982, IMC leased portions of the Additional and Uncharacterized Sites ("AUS") Operable Unit at the Crab Orchard Superfund Site ("the Site") from the government and manufactured various explosives for use in mining and other operations. In March 2002, the Department of Justice, the U.S. Department of the Interior and the EPA (together, "the Government Agencies") issued a special notice letter to General Dynamics Ordnance and Tactical Systems, Inc. ("General Dynamics"), one of the other potentially responsible parties ("PRPs") at the Site, to compel General Dynamics to perform the remedial investigation and feasibility study ("RI/FS") for the AUS Operable Unit. General Dynamics negotiated an AOC with the Government Agencies to conduct an extensive RI/FS at the Site under the direction of the U.S. Fish and Wildlife Service. General Dynamics asserted in August 2004 that the Company is jointly and severally liable, along with approximately eight other lessees and operators at the AUS Operable Unit, for alleged contamination of soils and groundwater resulting from historic operations, and has threatened to file a contribution claim against the Company and other parties for recovery of its costs incurred in connection with the RI/FS activities being conducted at the AUS Operable Unit. The Company and other PRPs who received demand letters from General Dynamics have explored settlement alternatives, but have not reached settlement to date. General Dynamics has completed the RI and initiated the FS, and the PRPs have entered into an agreement to enter into non-binding mediation, which has begun. While it is not possible at this time to determine with certainty the ultimate outcome of this matter, the Company believes, given the information currently available, that the final resolution of all known claims, after taking into account amounts already accrued, will not have a material adverse effect on its financial condition, results of operations and cash flows.

Products Liability Litigation

Beginning with lawsuits brought in July 1976, the Company is named as a defendant in personal injury lawsuits based on alleged exposure to asbestos-containing materials. A majority of the cases involve product liability claims based principally on allegations of past distribution of products containing asbestos. A limited number of the cases allege premises liability based on claims that individuals were exposed to asbestos while on the Company's property. Each case typically names dozens of corporate defendants in addition to the Company. The complaints generally seek monetary damages for personal injury or bodily injury resulting from alleged exposure to products containing asbestos. The Company's involvement in asbestos cases has been limited because it did not mine or

produce asbestos. Furthermore, in the Company's experience, a large percentage of these claims have never been substantiated and have been dismissed by the courts. The Company has not suffered an adverse verdict in a trial court proceeding related to asbestos claims and intends to continue to defend these lawsuits. When appropriate, the Company settles claims; however, amounts paid to settle and defend all asbestos claims have been immaterial. As of December 30, 2016, there were approximately 11,700 asbestos-related cases pending against the Company.

The Company estimates pending asbestos claims and claims that were incurred but not reported and related insurance recoveries, which are recorded on a gross basis in the unaudited condensed consolidated balance sheets. The Company's estimate of its liability for pending and future claims is based on claims experience over the past five years and covers claims either currently filed or expected to be filed over the next seven years. The Company believes that it has adequate amounts recorded related to these matters. While it is not possible at this time to determine with certainty the ultimate outcome of these asbestos-related proceedings, the Company believes, given the information currently available, that the ultimate resolutions of all known and anticipated future claims, after taking into account amounts already accrued, along with recoveries from insurance, will not have a material adverse effect on its financial condition, results of operations and cash flows.

Industrial Revenue Bonds

Through December 30, 2016, the Company exchanged title to $73.7 million of its plant assets in return for an equal amount of Industrial Revenue Bonds ("IRB") issued by Saint Louis County. The Company also simultaneously leased such assets back from Saint Louis County under capital leases expiring through December 2025, the terms of which provide it with the right of offset against the IRBs. The lease also provides an option for the Company to repurchase the assets at the end of the lease for nominal consideration. These transactions collectively result in a ten-year property tax abatement from the date the property is placed in service. Due to the right of offset, the capital lease obligations and IRB assets are recorded net in the consolidated balance sheets. The Company expects that the right of offset will be applied to payments required under these arrangements.

Interest Bearing Deferred Tax Obligation

As part of the integration of Questcor, the Company entered into an internal installment sale transaction related to certain Acthar intangible assets during the three months ended December 26, 2014. The installment sale transaction resulted in a taxable gain. In accordance with Internal Revenue Code Section 453A ("Section 453A") the gain is considered taxable in the period in which installment payments are received. During the three months ended December 25, 2015, the Company entered into similar transactions with certain intangible assets acquired in the acquisitions of Ikaria, Inc. and Therakos, Inc.. As of December 30, 2016, the Company had an aggregate $1,801.4 million of interest bearing U.S. deferred tax liabilities associated with outstanding installment notes. The GAAP calculation of interest associated with these deferred tax liabilities is subject to variable interest rates. The Company recognized interest expense associated with the Section 453A deferred tax liabilities of $15.9 million and $18.7 million for the three months ended December 30, 2016 and December 25, 2015, respectively.

The Company has reported Section 453A interest on its tax returns on the basis of its interpretation of the U.S. Internal Revenue Code and Regulations. Alternative interpretations of these provisions could result in additional interest payable on the deferred tax liability. Due to the inherent uncertainty in these interpretations, the Company has deferred the recognition of the benefit associated with the Company’s interpretation and maintains a corresponding liability of $30.3 million and $25.7 million as of December 30, 2016 and September 30, 2016, respectively. The balance of this liability is expected to increase over future periods until such uncertainty is resolved. Favorable resolution of this uncertainty would likely result in a material reversal of this liability and a benefit being recorded to interest expense within the unaudited condensed consolidated statements of income.

Acquisition-Related Litigation

Several putative class actions were filed by purported holders of Questcor common stock in connection with the Questcor Acquisition *(Hansen v. Thompson, et al., Heng v. Questcor Pharmaceuticals, Inc., et al., Buck v. Questcor Pharmaceuticals, Inc., et al., Ellerbeck v. Questcor Pharmaceuticals, Inc., et al., Yokem v. Questcor Pharmaceuticals, Inc., et al., Richter v. Questcor Pharmaceuticals, Inc., et al., Tramantano v. Questcor Pharmaceuticals, Inc., et al., Crippen v. Questcor Pharmaceuticals, Inc., et al., Patel v. Questcor Pharmaceuticals, Inc., et al.,* and *Postow v. Questcor Pharmaceuticals, Inc., et al.)*. The actions were consolidated on June 3, 2014. The consolidated complaint named as defendants, and generally alleged that, the directors of Questcor breached their fiduciary duties in connection with the acquisition by, among other things, agreeing to sell Questcor for inadequate consideration and pursuant to an inadequate process. The consolidated complaint also alleged that the Questcor directors breached their fiduciary duties by failing to disclose purportedly material information to shareholders in connection with the merger. The consolidated complaint also alleged, among other things, that the Company aided and abetted the purported breaches of fiduciary duty. The lawsuits sought various forms of relief, including but not limited to, rescission of the transaction, damages and attorneys' fees and costs.

On July 29, 2014, the defendants reached an agreement in principle with the plaintiffs in the consolidated actions, and that agreement was reflected in a Memorandum of Understanding ("MOU"). In connection with the settlement contemplated by the MOU, Questcor agreed to make certain additional disclosures related to the proposed transaction with the Company, which are contained in the Company's Current Report on Form 8-K filed with the SEC on July 30, 2014. Additionally, as part of the settlement and pursuant to the MOU, the Company agreed to forbear from exercising certain rights under the merger agreement with Questcor, as follows: the four business day period referenced in Section 5.3(e) of the merger agreement with Questcor was reduced to three business days. Consistent with the terms of the MOU, the parties entered into a formal stipulation of settlement in February 2015 and re-executed the stipulation of settlement on May 7, 2015 (collectively the "Stipulation of Settlement").

The Stipulation of Settlement was subject to customary conditions, including court approval. On May 8, 2015, the California Court denied plaintiffs' Motion for Preliminary Approval of Settlement. On October 23, 2015, the parties submitted a proposed Stipulation and Order re Dismissal With Prejudice dismissing the action with prejudice as to each of the named plaintiffs and without prejudice as to the remainder of the class and, on October 30, 2015, the California Court entered that Order.

Other Matters

The Company is a defendant in a number of other pending legal proceedings relating to present and former operations, acquisitions and dispositions. The Company does not expect the outcome of these proceedings, either individually or in the aggregate, to have a material adverse effect on its financial condition, results of operations and cash flows.

17. Financial Instruments and Fair Value Measurements

Fair value is defined as the exit price that would be received from the sale of an asset or paid to transfer a liability, using assumptions that market participants would use in pricing an asset or liability. The fair value guidance establishes a three-level fair value hierarchy, which maximizes the use of observable inputs and minimizes the use of unobservable inputs used in measuring fair value. The levels within the hierarchy are as follows:

Level 1— observable inputs such as quoted prices in active markets for identical assets or liabilities;

Level 2— significant other observable inputs that are observable either directly or indirectly; and

Level 3— significant unobservable inputs in which there is little or no market data, which requires the Company to develop its own assumptions.

The following tables provide a summary of the significant assets and liabilities that are measured at fair value on a recurring basis at the end of each period:

	December 30, 2016	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Debt and equity securities held in rabbi trusts	$ 33.6	$ 22.8	$ 10.8	$ —
Foreign exchange forward and option contracts	0.7	0.7	—	—
	$ 34.3	$ 23.5	$ 10.8	$ —
Liabilities:				
Deferred compensation liabilities	$ 32.5	$ —	$ 32.5	$ —
Contingent consideration and acquired contingent liabilities	250.5	—	—	250.5
Foreign exchange forward and option contracts	3.4	3.4	—	—
	$ 286.4	$ 3.4	$ 32.5	$ 250.5

	September 30, 2016	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Debt and equity securities held in rabbi trusts	$ 34.6	$ 23.1	$ 11.5	$ —
Foreign exchange forward and option contracts	0.2	0.2	—	—
	$ 34.8	$ 23.3	$ 11.5	$ —
Liabilities:				
Deferred compensation liabilities	$ 26.8	$ —	$ 26.8	$ —
Contingent consideration and acquired contingent liabilities	247.8	—	—	247.8
Foreign exchange forward and option contracts	1.6	1.6	—	—
	$ 276.2	$ 1.6	$ 26.8	$ 247.8

Debt and equity securities held in rabbi trusts. Debt securities held in rabbi trusts primarily consist of U.S. government and agency securities and corporate bonds. When quoted prices are available in an active market, the investments are classified as level 1. When quoted market prices for a security are not available in an active market, they are classified as level 2. Equity securities held in rabbi trusts primarily consist of U.S. common stocks, which are valued using quoted market prices reported on nationally recognized securities exchanges.

Foreign exchange forward and option contracts. Foreign currency option and forward contracts are used to economically manage the foreign exchange exposures of operations outside the U.S. Quoted prices are available in an active market; as such, these derivatives are classified as level 1.

Deferred compensation liabilities. The Company maintains a non-qualified deferred compensation plan in the U.S., which permits eligible employees of the Company to defer a portion of their compensation. A recordkeeping account is set up for each participant and the participant chooses from a variety of funds for the deemed investment of their accounts. The recordkeeping accounts generally correspond to the funds offered in the Company's U.S. tax-qualified defined contribution retirement plan and the account balance fluctuates with the investment returns on those funds.

Contingent consideration and acquired contingent liabilities. The Company maintains various contingent consideration and acquired contingent liabilities associated with the acquisitions of Questcor, Hemostasis products, Stratatech and CNS Therapeutics.

During the three months ended December 30, 2016, the Company reduced the probability-weighted present value associated with the achievement of the CNS Therapeutics contingent consideration, due to delays in the anticipated timing of FDA approval of a certain concentration of Gablofen, and recorded a reversal of the contingent consideration liability of $0.9 million within selling, general and administrative expenses. At December 30, 2016 and September 30, 2016, the fair value of the CNS Therapeutics contingent consideration was zero and $0.9 million, respectively.

The remaining contingent liability associated with the acquisition of Questcor, Inc. pertains the Company's license agreement with Novartis AG and Novartis Pharma AG (collectively "Novartis") related to the developmental product MNK-1141. At December 30, 2016, the total remaining payments under the license agreement shall not exceed $165.0 million. At December 30, 2016 and September 30, 2016, the fair value of the MNK-1141 contingent liability was $124.7 million and $123.4 million, respectively.

During the three months ended December 25, 2015, the Company paid the remaining obligation of $40.0 million CAD associated with contingent consideration obligations for BioVectra.

As part of the Hemostasis Acquisition, the Company provided contingent consideration to The Medicines Company in the form of sales based milestones associated with Raplixa and PreveLeak, and acquired contingent liabilities associated with The Medicines Company's prior acquisitions of the aforementioned products. The Company determined the fair value of the contingent consideration and acquired contingent liabilities based on an option pricing model to be $58.9 million and $11.2 million, respectively, at December 30, 2016. The fair value of the contingent consideration and acquired contingent liabilities based on an option pricing model were $57.7 million and $11.0 million, respectively, as of September 30, 2016.

As part of the Stratatech Acquisition, the Company provided contingent consideration to the Stratatech Corporation, primarily in the form of regulatory filing and approval milestones associated with the deep partial thickness and full thickness indications associated with the StrataGraft product. The Company assesses the likelihood of and timing of making such payments. The

Company determined the fair value of the contingent consideration associated with the Stratatech Acquisition to be $55.7 million and $54.9 million at December 30, 2016 and September 30, 2016, respectively.

The following table provides a summary of the changes in the Company's contingent consideration and acquired contingent liabilities:

Balance at September 30, 2016	$	247.8
Accretion expense		1.4
Fair value adjustment		1.3
Balance at December 30, 2016	$	250.5

Financial Instruments Not Measured at Fair Value

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable and the majority of other current assets and liabilities approximate fair value because of their short-term nature. The Company classifies cash on hand and deposits in banks, including commercial paper, money market accounts and other investments it may hold from time to time, with an original maturity of three months or less, as cash and cash equivalents (level 1). The fair value of restricted cash was equivalent to its carrying value of $19.1 million as of December 30, 2016 and September 30, 2016, respectively (level 1), which was included in prepaid expenses and other current assets and other assets on the unaudited condensed consolidated balance sheets. The Company entered into short-term investment certificates during the three months ended December 30, 2016. These certificates are carried at cost, which approximates fair value, of $11.1 million at December 30, 2016 (level 2). These certificates are included in prepaid expenses and other current assets on the unaudited condensed consolidating balance sheets. The Company's life insurance contracts are carried at cash surrender value, which is based on the present value of future cash flows under the terms of the contracts (level 3). Significant assumptions used in determining the cash surrender value include the amount and timing of future cash flows, interest rates and mortality charges. The fair value of these contracts approximates the carrying value of $67.6 million at December 30, 2016 and September 30, 2016, respectively. These contracts are included in other assets on the unaudited condensed consolidated balance sheets.

The carrying value of the Company's revolving credit facility and variable-rate receivable securitization approximates fair value due to the short-term nature of these instruments. The carrying value of the 4.00% term loan approximates the fair value of the instrument, as calculated using the discounted exit price, which is therefore classified as level 3. Since the quoted market prices for the Company's term loans and 8.00% and 9.50% debentures are not available in an active market, they are classified as level 2 for purposes of developing an estimate of fair value. The Company's 3.50%, 4.75%, 4.875%, 5.50%, 5.625% and 5.75% notes are classified as level 1, as quoted prices are available in an active market for these notes. The following table presents the carrying values and estimated fair values of the Company's long-term debt, excluding capital leases, as of the end of each period:

	December 30, 2016		September 30, 2016	
	Carrying Value	Fair Value	Carrying Value	Fair Value
Variable-rate receivable securitization	$ 250.0	$ 250.0	$ 235.0	$ 235.0
3.50% notes due April 2018	300.0	298.7	300.0	299.6
4.875% notes due April 2020	700.0	699.5	700.0	712.4
Term loans due March 2021	1,948.5	1,953.2	1,953.5	1,951.8
4.00% term loan due February 2022	6.5	6.5	7.1	7.1
9.50% debentures due May 2022	10.4	12.0	10.4	12.1
5.75% notes due August 2022	884.0	850.3	884.0	869.3
8.00% debentures due March 2023	4.4	4.9	4.4	4.9
4.75% notes due April 2023	600.0	520.9	600.0	539.5
5.625% notes due October 2023	738.0	682.4	740.0	710.2
5.50% notes due April 2025	695.0	615.7	700.0	663.6
Revolving credit facility	100.0	100.0	—	—

Concentration of Credit and Other Risks

Financial instruments that potentially subject the Company to concentrations of credit risk primarily consist of accounts receivable. The Company does not typically require collateral from customers. A portion of the Company's accounts receivable outside the U.S. includes sales to government-owned or supported healthcare systems in several countries, which are subject to payment delays. Payment is dependent upon the financial stability and creditworthiness of those countries' national economies.

The following table shows net sales attributable to distributors that accounted for 10% or more of the Company's total net sales:

	Three Months Ended	
	December 30, 2016	**December 25, 2015**
CuraScript, Inc.	43%	39%
McKesson Corporation	10%	16%

The following table shows accounts receivable attributable to distributors that accounted for 10% or more of the Company's gross accounts receivable at the end of each period:

	December 30, 2016	**September 30, 2016**
McKesson Corporation	28 %	30 %
Amerisource Bergen Corporation	15 %	15 %
CuraScript, Inc.	15 %	14 %
Cardinal Health, Inc.	10 %	10 %

The following table shows net sales attributable to products that accounted for 10% or more of the Company's total net sales:

	Three Months Ended	
	December 30, 2016	**December 25, 2015**
Acthar	39%	35%
Inomax	14%	14%

18. Segment Data

During the fourth quarter of fiscal 2016, the Company announced that it had entered into a definitive agreement to sell its Nuclear Imaging business to IBAM. The Nuclear Imaging business is deemed to be held for sale and the financial results of this business are presented as a discontinued operation. The sale was completed on January 27, 2017.

The two reportable segments are further described below:

- *Specialty Brands* includes branded pharmaceutical products and therapies; and
- *Specialty Generics* includes specialty generic pharmaceuticals and active pharmaceutical ingredients ("API") consisting of biologics, medicinal opioids, synthetic controlled substances, acetaminophen and other active ingredients.

Selected information by business segment was as follows:

	Three Months Ended	
	December 30, 2016	December 25, 2015
Net sales:		
Specialty Brands	$ 603.1	$ 543.2
Specialty Generics	212.9	257.6
Net sales of operating segments	816.0	800.8
Other [1]	13.9	10.4
Net sales	$ 829.9	$ 811.2
Operating income:		
Specialty Brands	$ 317.2	$ 269.1
Specialty Generics	52.7	115.2
Segment operating income	369.9	384.3
Unallocated amounts:		
Corporate and allocated expenses [2]	(181.4)	(44.6)
Intangible asset amortization	(175.7)	(173.4)
Restructuring and related charges, net [3]	(5.3)	(4.2)
Non-restructuring impairment charges	(214.3)	—
Operating (loss) income	$ (206.8)	$ 162.1

(1) Represents historical CMDS-related intercompany transactions that represent Mallinckrodt continuing operations under an ongoing supply agreement with the acquirer of the CMDS business.

(2) Includes administration expenses and certain compensation, legal, environmental and other costs not charged to the Company's operating segments.

(3) Includes restructuring-related accelerated depreciation.

Net sales by product family within the Company's segments are as follows:

	Three Months Ended	
	December 30, 2016	December 25, 2015
Acthar	$ 325.4	$ 286.7
Inomax	118.3	110.8
Ofirmev	72.5	66.9
Therakos immunotherapy	47.4	50.4
Hemostasis products	13.4	—
Other	26.1	28.4
Specialty Brands	603.1	543.2
Hydrocodone (API) and hydrocodone-containing tablets	23.2	36.7
Oxycodone (API) and oxycodone-containing tablets	24.3	28.9
Methylphenidate ER	22.0	31.2
Other controlled substances	104.9	109.7
Other products	38.5	51.1
Specialty Generics	212.9	257.6
Other [1]	13.9	10.4
Net sales	$ 829.9	$ 811.2

(1) Represents historical CMDS-related intercompany transactions that represent Mallinckrodt continuing operations under an ongoing supply agreement with the acquirer of the CMDS business.

19. Condensed Consolidating Financial Statements

Mallinckrodt International Finance, S.A. ("MIFSA"), an indirectly 100%-owned subsidiary of Mallinckrodt plc, is the borrower under the 3.50% notes due April 2018 and the 4.75% notes due April 2023 (collectively, "the Notes"), which are fully and unconditionally guaranteed by Mallinckrodt plc. The following information provides the composition of the Company's comprehensive income, assets, liabilities, equity and cash flows by relevant group within the Company: Mallinckrodt plc as guarantor of the Notes, MIFSA as issuer of the Notes and the other subsidiaries. There are no subsidiary guarantees related to the Notes.

Set forth on the following pages are the unaudited condensed consolidating financial statements for the three months ended December 30, 2016 and December 25, 2015, and as of December 30, 2016 and September 30, 2016. Eliminations represent adjustments to eliminate investments in subsidiaries and intercompany balances and transactions between or among Mallinckrodt plc, MIFSA and other subsidiaries. Unaudited condensed consolidating financial information for Mallinckrodt plc and MIFSA, on a standalone basis, has been presented using the equity method of accounting for subsidiaries.

MALLINCKRODT PLC
CONDENSED CONSOLIDATING BALANCE SHEET
As of December 30, 2016
(unaudited, in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Assets					
Current Assets:					
Cash and cash equivalents	$ 0.5	$ 44.5	$ 297.0	$ —	$ 342.0
Accounts receivable, net	—	—	431.0	—	431.0
Inventories	—	—	350.7	—	350.7
Prepaid expenses and other current assets	1.0	—	130.9	—	131.9
Current assets held for sale	—	—	310.9	—	310.9
Intercompany receivables	59.7	65.1	1,081.3	(1,206.1)	—
Total current assets	61.2	109.6	2,601.8	(1,206.1)	1,566.5
Property, plant and equipment, net	—	—	881.5	—	881.5
Goodwill	—	—	3,498.1	—	3,498.1
Intangible assets, net	—	—	9,000.5	—	9,000.5
Investment in subsidiaries	5,534.1	20,624.1	10,988.5	(37,146.7)	—
Intercompany loans receivable	3.5	—	3,325.9	(3,329.4)	—
Other assets	—	—	259.7	—	259.7
Total Assets	$ 5,598.8	$ 20,733.7	$ 30,556.0	$ (41,682.2)	$ 15,206.3
Liabilities and Shareholders' Equity					
Current Liabilities:					
Current maturities of long-term debt	$ —	$ 19.7	$ 251.5	$ —	$ 271.2
Accounts payable	0.1	0.1	111.9	—	112.1
Accrued payroll and payroll-related costs	—	—	76.1	—	76.1
Accrued interest	—	53.9	14.8	—	68.7
Accrued and other current liabilities	1.9	7.5	649.4	—	658.8
Current liabilities held for sale	—	—	120.3	—	120.3
Intercompany payables	612.5	467.1	126.5	(1,206.1)	—
Total current liabilities	614.5	548.3	1,350.5	(1,206.1)	1,307.2
Long-term debt	—	5,860.6	20.2	—	5,880.8
Pension and postretirement benefits	—	—	136.4	—	136.4
Environmental liabilities	—	—	73.0	—	73.0
Deferred income taxes	—	—	2,398.1	—	2,398.1
Other income tax liabilities	—	—	70.4	—	70.4
Intercompany loans payable	—	3,329.4	—	(3,329.4)	—
Other liabilities	—	7.0	349.1	—	356.1
Total Liabilities	614.5	9,745.3	4,397.7	(4,535.5)	10,222.0
Shareholders' Equity	4,984.3	10,988.4	26,158.3	(37,146.7)	4,984.3
Total Liabilities and Shareholders' Equity	$ 5,598.8	$ 20,733.7	$ 30,556.0	$ (41,682.2)	$ 15,206.3

MALLINCKRODT PLC
CONDENSED CONSOLIDATING BALANCE SHEET
As of September 30, 2016
(unaudited, in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Assets					
Current Assets:					
Cash and cash equivalents	$ 0.3	$ 25.0	$ 255.2	$ —	$ 280.5
Accounts receivable, net	—	—	465.8	—	465.8
Inventories	—	—	335.6	—	335.6
Prepaid expenses and other current assets	1.4	0.1	114.4	—	115.9
Current assets held for sale	—	—	308.8	—	308.8
Intercompany receivables	88.9	473.8	1,081.4	(1,644.1)	—
Total current assets	90.6	498.9	2,561.2	(1,644.1)	1,506.6
Property, plant and equipment, net	—	—	844.0	—	844.0
Goodwill	—	—	3,705.3	—	3,705.3
Intangible assets, net	—	—	9,182.3	—	9,182.3
Investment in subsidiaries	5,657.8	20,168.4	11,020.0	(36,846.2)	—
Intercompany loans receivable	143.5	—	3,159.4	(3,302.9)	—
Other assets	—	—	260.5	—	260.5
Total Assets	$ 5,891.9	$ 20,667.3	$ 30,732.7	$ (41,793.2)	$ 15,498.7
Liabilities and Shareholders' Equity					
Current Liabilities:					
Current maturities of long-term debt	$ —	$ 19.8	$ 236.5	$ —	$ 256.3
Accounts payable	0.2	—	109.9	—	110.1
Accrued payroll and payroll-related costs	—	—	116.0	—	116.0
Accrued interest	—	79.3	1.3	—	80.6
Accrued and other current liabilities	2.2	7.5	541.2	—	550.9
Current liabilities held for sale	—	—	120.8	—	120.8
Intercompany payables	618.8	462.6	562.7	(1,644.1)	—
Total current liabilities	621.2	569.2	1,688.4	(1,644.1)	1,234.7
Long-term debt	—	5,767.8	20.9	—	5,788.7
Pension and postretirement benefits	—	—	144.9	—	144.9
Environmental liabilities	—	—	73.4	—	73.4
Deferred income taxes	—	—	2,581.4	—	2,581.4
Other income tax liabilities	—	—	67.7	—	67.7
Intercompany loans payable	—	3,302.9	—	(3,302.9)	—
Other liabilities	—	7.4	329.8	—	337.2
Total Liabilities	621.2	9,647.3	4,906.5	(4,947.0)	10,228.0
Shareholders' Equity	5,270.7	11,020.0	25,826.2	(36,846.2)	5,270.7
Total Liabilities and Shareholders' Equity	$ 5,891.9	$ 20,667.3	$ 30,732.7	$ (41,793.2)	$ 15,498.7

MALLINCKRODT PLC
CONDENSED CONSOLIDATING STATEMENT OF COMPREHENSIVE INCOME
For the three months ended December 30, 2016
(unaudited, in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Net sales	$ —	$ —	$ 829.9	$ —	$ 829.9
Cost of sales	—	—	384.1	—	384.1
Gross profit	—	—	445.8	—	445.8
Selling, general and administrative expenses	13.4	0.2	354.7	—	368.3
Research and development expenses	—	—	66.2	—	66.2
Restructuring charges, net	—	—	3.8	—	3.8
Non-restructuring impairment charges	—	—	214.3	—	214.3
Operating (loss) income	(13.4)	(0.2)	(193.2)	—	(206.8)
Interest expense	(2.9)	(81.1)	(17.9)	10.6	(91.3)
Interest income	—	0.1	11.0	(10.6)	0.5
Other income (expense), net	1.8	0.7	(3.4)	—	(0.9)
Intercompany fees	(4.4)	—	4.4	—	—
Equity in net income (loss) of subsidiaries	(136.5)	35.2	(44.5)	145.8	—
(Loss) income from continuing operations before income taxes	(155.4)	(45.3)	(243.6)	145.8	(298.5)
Income tax benefit	(2.2)	(0.3)	(119.2)	—	(121.7)
(Loss) income from continuing operations	(153.2)	(45.0)	(124.4)	145.8	(176.8)
Income from discontinued operations, net of income taxes	—	0.4	23.2	—	23.6
Net (loss) income	(153.2)	(44.6)	(101.2)	145.8	(153.2)
Other comprehensive loss, net of tax	13.1	13.1	26.0	(39.1)	13.1
Comprehensive (loss) income	$ (140.1)	$ (31.5)	$ (75.2)	$ 106.7	$ (140.1)

MALLINCKRODT PLC
CONDENSED CONSOLIDATING STATEMENT OF COMPREHENSIVE INCOME
For the three months ended December 25, 2015
(unaudited, in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Net sales	$ —	$ —	$ 811.2	$ —	$ 811.2
Cost of sales	—	—	360.3	—	360.3
Gross profit	—	—	450.9	—	450.9
Selling, general and administrative expenses	10.4	0.3	212.6	—	223.3
Research and development expenses	—	—	61.4	—	61.4
Restructuring charges, net	—	—	4.1	—	4.1
Operating (loss) income	(10.4)	(0.3)	172.8	—	162.1
Interest expense	(68.0)	(81.9)	(21.0)	73.1	(97.8)
Interest income	—	—	73.3	(73.1)	0.2
Other income (expense), net	67.7	1.7	(67.4)	—	2.0
Intercompany fees	(3.2)	(0.1)	3.3	—	—
Equity in net income of subsidiaries	211.0	312.0	271.7	(794.7)	—
Income (loss) from continuing operations before income taxes	197.1	231.4	432.7	(794.7)	66.5
Income tax benefit	(14.0)	—	(23.3)	—	(37.3)
Income from continuing operations	211.1	231.4	456.0	(794.7)	103.8
Income from discontinued operations, net of income taxes	—	40.3	67.0	—	107.3
Net income	211.1	271.7	523.0	(794.7)	211.1
Other comprehensive (loss) income, net of tax	(66.2)	(66.2)	(132.5)	198.7	(66.2)
Comprehensive income	$ 144.9	$ 205.5	$ 390.5	$ (596.0)	$ 144.9

MALLINCKRODT PLC
CONDENSED CONSOLIDATING STATEMENT OF CASH FLOWS
For the three months ended December 30, 2016
(unaudited, in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Cash Flows From Operating Activities:					
Net cash provided by (used in) operating activities	$ 17.4	$ (94.0)	$ 272.2	$ —	$ 195.6
Cash Flows From Investing Activities:					
Capital expenditures	—	—	(65.2)	—	(65.2)
Acquisitions and intangibles, net of cash acquired	—	—	(1.8)	—	(1.8)
Proceeds from disposal of discontinued operations, net of cash	—	—	—	—	—
Intercompany loan investment, net	—	—	(424.7)	424.7	—
Investment in subsidiary	—	(260.0)	—	260.0	—
Restricted cash	—	—	—	—	—
Other	—	—	(10.2)	—	(10.2)
Net cash used in investing activities	—	(260.0)	(501.9)	684.7	(77.2)
Cash Flows From Financing Activities:					
Issuance of external debt	—	175.0	15.0	—	190.0
Repayment of external debt and capital leases	—	(86.2)	(0.5)	—	(86.7)
Debt financing costs	—	—	—	—	—
Proceeds from exercise of share options	0.4	—	—	—	0.4
Repurchase of shares	(158.8)	—	—	—	(158.8)
Intercompany loan borrowings, net	140.0	284.7	—	(424.7)	—
Capital contribution	—	—	260.0	(260.0)	—
Other	1.2	—	—	—	1.2
Net cash (used in) provided by financing activities	(17.2)	373.5	274.5	(684.7)	(53.9)
Effect of currency rate changes on cash	—	—	(3.0)	—	(3.0)
Net increase in cash and cash equivalents	0.2	19.5	41.8	—	61.5
Cash and cash equivalents at beginning of period	0.3	25.0	255.2	—	280.5
Cash and cash equivalents at end of period	$ 0.5	$ 44.5	$ 297.0	$ —	$ 342.0

MALLINCKRODT PLC
CONDENSED CONSOLIDATING STATEMENT OF CASH FLOWS
For the three months ended December 25, 2015
(unaudited, in millions)

	Mallinckrodt plc	Mallinckrodt International Finance S.A.	Other Subsidiaries	Eliminations	Consolidated
Cash Flows From Operating Activities:					
Net cash provided by (used in) operating activities	$ 39.2	$ 51.9	$ 220.3	$ —	$ 311.4
Cash Flows From Investing Activities:					
Capital expenditures	—	—	(49.0)	—	(49.0)
Proceeds from disposal of discontinued operations, net of cash	—	235.4	28.6	—	264.0
Intercompany loan investment, net	—	(105.8)	(127.0)	232.8	—
Investment in subsidiary	—	(46.2)	—	46.2	—
Restricted cash	—	—	(0.1)	—	(0.1)
Other	—	—	0.7	—	0.7
Net cash provided from (used in) investing activities	—	83.4	(146.8)	279.0	215.6
Cash Flows From Financing Activities:					
Issuance of external debt	—	—	62.0	—	62.0
Repayment of external debt and capital leases	—	(128.9)	(0.7)	—	(129.6)
Debt financing costs	—	—	(0.1)	—	(0.1)
Excess tax benefit from share-based compensation	—	—	—	—	—
Proceeds from exercise of share options	3.6	—	—	—	3.6
Repurchase of shares	(275.4)	—	—	—	(275.4)
Intercompany loan borrowings, net	232.8	—	—	(232.8)	—
Capital contribution	—	—	46.2	(46.2)	—
Other	—	—	(30.0)	—	(30.0)
Net cash (used in) provided by financing activities	(39.0)	(128.9)	77.4	(279.0)	(369.5)
Effect of currency rate changes on cash	—	—	(1.5)	—	(1.5)
Net increase in cash and cash equivalents	0.2	6.4	149.4	—	156.0
Cash and cash equivalents at beginning of period	0.1	152.1	213.7	—	365.9
Cash and cash equivalents at end of period	$ 0.3	$ 158.5	$ 363.1	$ —	$ 521.9

20. Subsequent Events

Commitments and Contingencies

In January 2017, the FTC, Maryland, Texas, Washington, New York, Alaska and the Company entered into an agreement to resolve the ongoing investigation into Questcor's acquisition of MNK-1141 for a one-time cash payment of $102.0 million and an agreement to license MNK-1141 to a third party designated by the FTC for possible development in Infantile Spasms (IS) and Nephrotic Syndrome (NS) in the U.S. The settlement was approved by the court on January 30, 2017.

In January 2017, the Company received a subpoena from the SEC for documents related to the Company’s public statements, filings and other disclosures regarding Acthar sales, profits, revenue, promotion and pricing.

On January 23, 2017, a putative class action lawsuit was filed against the Company and CEO Mark Trudeau in the U.S. District Court for the District of Columbia, captioned *Patricia A. Shenk v. Mallinckrodt plc, et al.*, No. 17-cv-00145-EGS. The complaint purports to be brought on behalf of all persons who purchased Mallinckrodt’s publicly traded securities on a domestic exchange between November 25, 2014 and January 18, 2017. The lawsuit generally alleges that the Company made false or misleading statements related to Acthar and Synacthen to artificially inflate the price of the Company’s stock. In particular, the complaint alleges a failure by the Company to provide accurate disclosures concerning the long-term sustainability of Acthar revenues, and the exposure of Acthar to Medicare and Medicaid reimbursement rates. On January 26, 2017, a second putative class action lawsuit, captioned *Jyotindra Patel v. Mallinckrodt plc, et al.*, No. 1:17-cv-00171, was filed against the same defendants named in the *Shenk* lawsuit in the U.S. District Court for the District of Columbia. The *Patel* complaint purports to be brought on behalf of shareholders during same period of time as that set forth in the *Shenk* lawsuit and asserts claims similar to those set forth in the *Shenk* lawsuit.

Investment in Mesoblast

In December 2016, the Company entered into an equity purchase agreement with Mesoblast Limited ("Mesoblast"). In addition to the equity shares, the Company received the rights to an exclusivity period of nine months to conclude commercial and development agreements for Mesoblast's therapy products used to treat acute graft versus host disease and chronic low back pain. In January 2017, $21.5 million of consideration was remitted to Mesoblast in exchange for the equity shares and rights to the exclusivity period.

Divestitures

The Company's sale of its Nuclear Imaging business to IBAM was completed on January 27, 2017 for approximately $690.0 million before tax impacts, including up-front consideration of approximately $574.0 million, up to $77.0 million of contingent consideration and the assumption of certain liabilities.

On January 30, 2017, the Company announced that it had entered into a definitive agreement to sell its Intrathecal Therapy business to Piramal Enterprises Limited's subsidiary in the U.K., Piramal Critical Care, for approximately $203.0 million, including fixed consideration of $171.0 million and contingent consideration of up to $32.0 million. The transaction is expected to be completed in the first quarter of 2017.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and the accompanying notes included in this Transition Report on Form 10-Q. The following discussion may contain forward-looking statements that reflect our plans, estimates and beliefs and involve risks, uncertainties and assumptions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to these differences include those discussed in Item 1A. Risk Factors of our Annual Report on Form 10-K for the fiscal year ended September 30, 2016, filed with the United States ("U.S.") Securities and Exchange Commission ("the SEC") on November 29, 2016.

We own or have rights to use the trademarks and trade names that we use in conjunction with the operation of our business. One of the more important trademarks that we own or have rights to use that appears in this Transition Report on Form 10-Q is "Mallinckrodt," which is a registered trademark or the subject of pending trademark applications in the U.S. and other jurisdictions. Solely for convenience, we only use the ™ or ® symbols the first time any trademark or trade name is mentioned in the following discussion. Such references are not intended to indicate in any way that we will not assert, to the fullest extent permitted under applicable law, our rights to our trademarks and trade names. Each trademark or trade name of any other company appearing in the following discussion is, to our knowledge, owned by such other company.

Overview

We are a global business that develops, manufactures, markets and distributes branded and generic specialty pharmaceutical products and therapies. Therapeutic areas of focus include autoimmune and rare disease specialty areas (including neurology, rheumatology, nephrology, ophthalmology and pulmonology); immunotherapy and neonatal critical care respiratory therapies; analgesics and hemostasis products; and central nervous system drugs.

We operate our business in two reportable segments, which are further described below:

- *Specialty Brands* includes branded pharmaceutical products and therapies; and
- *Specialty Generics* includes specialty generic pharmaceuticals and active pharmaceutical ingredients ("API") consisting of biologics, medicinal opioids, synthetic controlled substances, acetaminophen and other active ingredients.

For further information on our business and products, refer to our Annual Report on Form 10-K for the year ended September 30, 2016, filed with the SEC on November 29, 2016.

Significant Events

Acquisitions

In August 2016, we acquired Stratatech Corporation, through the acquisition of all outstanding common stock for upfront consideration of $76.0 million and contingent milestone payments, which are primarily regulatory, and royalty obligations that could result in up to $121.0 million of additional consideration ("the Stratatech Acquisition"). Stratatech is a regenerative medicine company focused on the development of unique, proprietary skin substitute products. Developmental products include StrataGraft® regenerative skin tissue and a technology platform for genetically enhanced skin tissues. The acquisition was funded with cash on hand.

In February 2016, we acquired three commercial stage topical hemostasis drugs from The Medicines Company ("the Hemostasis Acquisition") - RECOTHROM® Thrombin topical (Recombinant), PreveLeak™ Surgical Sealant, and RAPLIXA™ (Fibrin Sealant (Human)) - for upfront consideration of $173.5 million, inclusive of existing inventory, and contingent sales-based milestone payments that could result in up to $395.0 million of additional consideration. The acquisition was funded with cash on hand.

Divestitures

On August 24, 2016, the Company announced that it had entered into a definitive agreement to sell its Nuclear Imaging business to IBA Molecular ("IBAM") for approximately $690.0 million before tax impacts, including up-front consideration of approximately $574.0 million, up to $77.0 million of contingent consideration and the assumption of certain liabilities. The Nuclear Imaging business was deemed to be held for sale and the financial results of this business are presented as a discontinued operation. As a result, prior year balances have been recast to present the financial results of the Nuclear Imaging business as a discontinued operation. The sale was completed on January 27, 2017.

On November 27, 2015, we completed the sale of our CMDS business to Guerbet S.A. ("Guerbet") for cash consideration of approximately $270.0 million, subject to yet to be resolved net working capital adjustments. The financial results for the CMDS business are presented as a discontinued operation.

Business Factors Influencing the Results of Operations

Products

The Specialty Generics segment has and may continue to experience customer consolidation and increased generic product approvals leading to increased competition, which is expected to result in further downward pressure on net sales, operating income and cash flow from operations. Net sales from the Specialty Generics segment, excluding Methylphenidate ER which is discussed further below, for the three months ended December 30, 2016 were $190.9 million compared with $226.4 million during the three months ended December 25, 2015.

In November 2014, we were informed by the U.S. Food and Drug Administration ("FDA") that it believes that our Methylphenidate ER products may not be therapeutically equivalent to the category reference listed drug and the FDA reclassified Methylphenidate ER from freely substitutable at the pharmacy level (class AB) to presumed to be therapeutically inequivalent (class BX). The FDA has indicated that it has not identified any serious safety concerns with the products. We continue to market our Methylphenidate ER products as a class BX-rated drug. The FDA's action to reclassify our Methylphenidate ER products had, and is expected to continue to have, a negative impact on net sales and operating income unless the FDA reverses its decision. On October 18, 2016, the FDA initiated proceedings, proposing to withdraw approval of Mallinckrodt's Abbreviated New Drug Application ("ANDA") for Methylphenidate ER. The Company has requested a hearing in the withdrawal proceedings and the deadline for submitting documentation supporting the request for a hearing is March 20, 2017. The Company plans to vigorously set forth its position in the withdrawal proceedings. A potential outcome of the withdrawal proceedings is that our Methylphenidate ER products may lose their FDA approval, which could have a material, negative impact to our Specialty Generics segment. Net sales of our Methylphenidate ER products during the three months ended December 30, 2016 were $22.0 million compared with $31.2 million during the three months ended December 25, 2015.

As discussed above, the Specialty Generics segment has experienced customer consolidation and increased competition that have and are expected to result in further downward pressure to net sales and operating income in this segment. During the three months ended December 30, 2016, the FDA approved new products that are expected to compete with the Company's Methylphenidate ER products and one competitor launched their products. Additional products expected to compete with the Company's Methylphenidate ER products may be launched during fiscal 2017. All of these products have a class AB rating compared with the class BX rating on the Company's Methylphenidate ER products. It is uncertain how these product approvals may impact the FDA's withdrawal proceedings associated with the Company's Methylphenidate ER products.

The Company determined that these events represented a triggering event and the Company performed an assessment of the goodwill associated with the Specialty Generics reporting unit as of December 30, 2016. The Company performed a goodwill impairment test and recognized a $207.0 million goodwill impairment in the Specialty Generics segment. Following this impairment charge there is no remaining goodwill associated with the Specialty Generics segment.

Restructuring Initiatives

We continue to realign our cost structure due to the changing nature of our business and look for opportunities to achieve operating efficiencies.

During fiscal 2013, our Board of Directors approved a restructuring program in the amount of $100.0 million to $125.0 million ("the 2013 Mallinckrodt Program") that was planned to occur over a three-year period from approval of the program, with an anticipated two-year cost recovery period. The 2013 Mallinckrodt Program is substantially complete.

In July 2016, our Board of Directors approved a $100.0 million to $125.0 million restructuring program ("the 2016 Mallinckrodt Program") designed to further improve its cost structure, as we continue to transform our business. The 2016 Mallinckrodt Program is expected to include actions across both the Specialty Brands and Specialty Generics segments, as well as within corporate functions. There is no specified time period associated with the 2016 Mallinckrodt Program. Through December 30, 2016, we incurred restructuring charges of $13.5 million under the 2016 Mallinckrodt Program, which are expected to generate savings, substantially within our SG&A expenses. In addition to the 2016 Mallinckrodt Program, we take certain restructuring actions to generate synergies from our acquisitions.

Research and Development Investment

We expect to continue to pursue targeted investments in R&D activities, both for existing products and the development of new portfolio assets. We intend to focus our R&D investments in the specialty pharmaceuticals areas, specifically investments to support our Specialty Brands, where we believe there is the greatest opportunity for growth and profitability. Our Specialty Brands include medicines for pain management, acute and critical care, and autoimmune and rare diseases (“ARD”). Our primary focus for the latter includes the therapeutic areas of neurology, rheumatology, nephrology, pulmonology and ophthalmology.

Specialty Brands. We devote significant R&D resources to our branded products. Our R&D investments center on building a diverse, durable portfolio of innovative therapies that provide value to patients, physicians and payers. We are leveraging both organic development and acquiring late stage development assets through the execution of our “acquire to invest” strategy to facilitate organic growth. Under this strategy, we look to acquire durable, but currently under-resourced assets for which we believe we can accelerate growth and expand reach to patients with unmet medical needs.

Data generation is an important strategic driver for key products in order to extend evidence in approved uses, label enhancements and new indications. Our strategy is realized through investments in both clinical and health economic activities. We are committed to supporting research that helps advance the understanding and treatment of a variety of different disease states that will further the understanding and development of our currently marketed products, including Acthar®, Ofirmev®, Inomax, and Therakos immunotherapy.

Our "acquire to invest" strategy also includes the acquisition of early and late stage development products to meet the needs of underserved patient populations. Under our strategy we continue the development process and perform clinical trials to support FDA approval of new products. The most significant development products in our pipeline include Terlipressin, StrataGraft and MNK-1141 (the product formerly described as Synacthen Depot) in the U.S. Terlipressin is being investigated for the treatment of Hepatorenal Syndrome ("HRS") type 1, an acute, rare and life-threatening condition requiring hospitalization, with no currently approved therapy in the U.S. In July 2016, the Company enrolled the first patient in the company's Phase 3 clinical study to evaluate the efficacy and safety of terlipressin (for injection) in subjects with HRS type 1. StrataGraft is an investigational product in Phase 3 development for treatment of severe, deep partial thickness burns and Phase 2 development for treatment of severe, full thickness burns. In 2012, the FDA granted StrataGraft orphan product status, and the product is being developed as a biologic to be filed under a biologic license application that would confer regulatory protection until 2032. MNK-1141 is a depot formulation of Synacthen (tetracosactide), a synthetic 24 amino acid melanocortin receptor agonist. In August 2016, we announced that the FDA has granted the company's request for fast track designation for its Investigational New Drug ("IND") application for MNK-1141 in the treatment of Duchenne muscular dystrophy ("DMD"). The FDA's fast track designation is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions that fill an unmet medical need.

Specialty Generics. Specialty Generics development is focused on hard-to-manufacture pharmaceuticals with difficult-to-replicate pharmacokinetic profiles. Our Specialty Generics pipeline portfolio consists of several products in various stages of development. We currently do most of our development work at our Specialty Generics headquarters and technical development center in Webster Groves, Missouri.

Results of Operations

Three Months Ended December 30, 2016 Compared with Three Months Ended December 25, 2015

Net Sales

Net sales by geographic area were as follows (dollars in millions):

	Three Months Ended		Percentage Change
	December 30, 2016	December 25, 2015	
U.S.	$ 763.7	$ 740.2	3.2 %
Europe, Middle East and Africa	52.8	49.3	7.1
Other	13.4	21.7	(38.2)
Net sales	$ 829.9	$ 811.2	2.3

Net sales for the three months ended December 30, 2016 increased $18.7 million, or 2.3%, to $829.9 million, compared with $811.2 million for the three months ended December 25, 2015. This increase was primarily driven by growth in the Specialty Brands segment with higher volume for Acthar and Ofirmev, benefits of Inomax contracting and the fiscal 2016 Hemostasis Acquisition. These increases were partially offset by decreased net sales in the Specialty Generics segment attributable to increased competition and customer consolidation, which has resulted in downward pricing pressure. For further information on changes in our net sales, refer to "Business Segment Results" within Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Operating Income

Gross profit. Gross profit for the three months ended December 30, 2016 decreased $5.1 million, or 1.1%, to $445.8 million, compared with $450.9 million for the three months ended December 25, 2015. The decrease in gross profit primarily resulted from a $53.2 million decrease in gross profit from the Specialty Generics segment. This was partially offset by higher net sales in the Specialty Brands segment, primarily due to volume growth across our key brands, and a $12.6 million decrease in expense associated with fair value adjustments of acquired inventory. Gross profit margin was 53.7% for the three months ended December 30, 2016, compared with 55.6% for the three months ended December 25, 2015. The decrease in gross profit margin was primarily attributable to the increased price competition in the Specialty Generics business, partially offset by a higher percentage of overall sales relating to the higher-margin Specialty Brands business.

Selling, general and administrative expenses ("SG&A"). SG&A expenses for the three months ended December 30, 2016 were $368.3 million, compared with $223.3 million for the three months ended December 25, 2015, an increase of $145.0 million, or 64.9%. The increase was primarily attributable to charges during the three months ended December 30, 2016 related to a $102.0 million settlement with the Federal Trade Commission ("FTC") and the states of Maryland, Texas, Washington, New York and Alaska (collectively, "the Settling States") and $45.0 million associated with the recognition of previously deferred pension related losses upon lump sum distribution to current and former employees under our pension plan termination. Additional charges from deferred pension related losses are anticipated in the first half of calendar 2017 with the final settlement of outstanding obligations under these plans. The three months ended December 25, 2015, included $11.5 million of legal reserve accruals. The remaining $9.5 million increase from the three months ended December 30, 2016 compared with December 25, 2015 is comprised of various minor increases and decreases. SG&A expenses were 44.4% of net sales for the three months ended December 30, 2016 and 27.5% of net sales for the three months ended December 25, 2015. The higher percentage of net sales is attributable to the aforementioned charges with the FTC and the Settling States along with the pension related settlement losses, which collectively represented 17.7% of net sales for the three months ended December 30, 2016.

Research and development expenses ("R&D"). R&D expenses increased $4.8 million, or 7.8%, to $66.2 million for the three months ended December 30, 2016, compared with $61.4 million for the three months ended December 25, 2015. Current R&D activities focus on performing clinical studies and publishing clinical and non-clinical experiences and evidence that support health economic and patient outcomes. As a percentage of net sales, R&D expenses were 8.0% and 7.6% for the three months ended December 30, 2016 and December 25, 2015, respectively.

Restructuring charges, net. During the three months ended December 30, 2016, we recorded $5.3 million of restructuring and related charges, net, including $1.5 million of accelerated depreciation in SG&A and cost of sales, primarily related to employee severance and benefits across our Specialty Brands segment and corporate functions. During the three months ended December 25, 2015, we recorded restructuring and related charges, net, of $4.2 million, including $0.1 million of accelerated depreciation in cost of sales, primarily related to employee severance benefits across both of our operating segments and corporate functions.

Non-restructuring impairment charges. During the three months ended December 30, 2016, we recorded a $207.0 million impairment charge associated with our Specialty Generics segment and a $7.3 million impairment of a license associated with a product the Company elected to discontinue.

Non-Operating Items

Interest expense and interest income. During the three months ended December 30, 2016 and December 25, 2015, net interest expense was $90.8 million and $97.6 million, respectively. The decrease in net interest expense was impacted by a $2.8 million decrease in interest accrued on deferred tax liabilities associated with outstanding installment notes, due to payments that reduced the deferred tax liability balance. The decrease was also driven by lower average outstanding balances on the revolving credit facility and term loan borrowings. Interest expense during the three months ended December 30, 2016 and December 25, 2015 included $6.5 million and $6.7 million, respectively, of non-cash interest expense.

Other income (expense), net. During the three months ended December 30, 2016, we recorded other expense, net, of $0.9 million and during the three months ended December 25, 2015, we recorded other income, net, of $2.0 million, both of which represented miscellaneous items, including gains and losses on intercompany financing, foreign currency transactions and related hedging instruments.

Income tax expense (benefit). Income tax benefit was $121.7 million on a loss from continuing operations before income taxes of $298.5 million for the three months ended December 30, 2016 and an income tax benefit of $37.3 million on income from continuing operations before income taxes of $66.5 million for the three months ended December 25, 2015. Our effective tax rates were 40.8% and negative 56.1% for the three months ended December 30, 2016 and December 25, 2015, respectively. The effective tax rate for the three months ended December 30, 2016 was impacted by receiving $12.7 million of tax benefit associated with an adjustment to the Company’s wholly owned partnership investment, $0.6 million of tax benefit associated with $207.0 million of goodwill impairment, $36.6 million of tax benefit associated with the $102.0 million settlement with governmental authorities, and $72.3 million of tax benefit associated with the rate difference between U.K. and non-U.K. jurisdictions (excluding

impact of above referenced settlement and impairment).The effective tax rate for the three months ended December 25, 2015 was impacted by $3.3 million of tax benefit associated with accrued income tax liabilities and uncertain tax positions, $3.6 million of tax benefit associated with U.S. credits and $45.1 million of tax benefit associated with the rate difference between U.K. and non-U.K. jurisdictions.

Income from discontinued operations, net of income taxes. We recorded income from discontinued operations of $23.6 million and $107.3 million during the three months ended December 30, 2016 and December 25, 2015, respectively. Income from discontinued operations for the three months ended December 30, 2016, primarily represents the operating results associated with the Nuclear Imaging business that was classified as held for sale during the period. Income from discontinued operations for the three months ended December 25, 2015, includes a $97.0 million gain on the disposal of the CMDS business and $12.1 million of income from the operating results of the Nuclear Imaging business.

Business Segment Results

The businesses included within our reportable segments are described below:

Specialty Brands

- includes branded pharmaceutical drugs for autoimmune and rare diseases, neonatal critical care respiratory therapeutics and immunotherapy, and pain management.

Specialty Generics

- includes specialty generic pharmaceuticals and API consisting of biologics, medicinal opioids, synthetic controlled substances, acetaminophen and other active ingredients.

Management measures and evaluates our operating segments based on segment net sales and operating income. Management excludes certain corporate expenses from segment operating income. In addition, certain amounts that management considers to be non-recurring or non-operational are excluded from segment operating income because management evaluates the operating results of the segments excluding such items. These items include net sales and expenses associated with sales of products to the acquirer of the CMDS business under an ongoing supply agreement, intangible asset amortization, impairments and net restructuring and related charges. Although these amounts are excluded from segment operating income, as applicable, they are included in reported consolidated operating income and in the reconciliations presented below. Selected information by business segment is as follows:

Three Months Ended December 30, 2016 Compared with Three Months Ended December 25, 2015

Net Sales

Net sales by segment are shown in the following table (dollars in millions):

	Three Months Ended		Percentage Change
	December 30, 2016	December 25, 2015	
Specialty Brands	$ 603.1	$ 543.2	11.0 %
Specialty Generics	212.9	257.6	(17.4)
Net sales of operating segments	816.0	800.8	1.9
Other [1]	13.9	10.4	33.7
Net sales	$ 829.9	$ 811.2	2.3

(1) Represents net sales from an ongoing, post-divestiture supply agreement with the acquirer of the CMDS business. Amounts for periods prior to the divestiture represent the reclassification of intercompany sales to third-party sales to conform with the expected presentation of the ongoing supply agreement.

Specialty Brands. Net sales for the three months ended December 30, 2016 increased $59.9 million to $603.1 million, compared with $543.2 million for the three months ended December 25, 2015. The increase in net sales was primarily driven by a $38.7 million or 13.5% increase in Acthar net sales compared with the three months ended December 25, 2015 due to increased volume. The fiscal 2016 acquisition of Hemostasis products increased net sales by $13.4 million. Inomax net sales increased by $7.5 million due to a favorable contracting cycle while Ofirmev net sales increased $5.6 million due to volume. Therakos net sales decreased by $3.0 million primarily due to a product supply disruption.

Net sales for Specialty Brands by geography were as follows (dollars in millions):

	Three Months Ended		
	December 30, 2016	December 25, 2015	Percentage Change
U.S.	$ 585.2	$ 524.8	11.5 %
Europe, Middle East and Africa	16.2	17.0	(4.7)
Other	1.7	1.4	21.4
Net sales	$ 603.1	$ 543.2	11.0

Net sales for Specialty Brands by key products were as follows (dollars in millions):

	Three Months Ended		
	December 30, 2016	December 25, 2015	Percentage Change
Acthar	$ 325.4	$ 286.7	13.5 %
Inomax	118.3	110.8	6.8
Ofirmev	72.5	66.9	8.4
Therakos immunotherapy	47.4	50.4	(6.0)
Hemostasis products	13.4	—	—
Other	26.1	28.4	(8.1)
Specialty Brands	$ 603.1	$ 543.2	11.0

Specialty Generics. Net sales for the three months ended December 30, 2016 decreased $44.7 million, or 17.4%, to $212.9 million, compared with $257.6 million for the three months ended December 25, 2015. The decrease in net sales was driven by decreases in all product categories, most notably decreases of $13.5 million, $9.2 million and $12.6 million in hydrocodone related products, Methylphenidate ER and other products, respectively. The Specialty Generics segment has and may continue to experience customer consolidation that has led to increased competition, which resulted in decreased net sales. Methylphenidate ER net sales continue to be negatively impacted by the FDA reclassification of these products to therapeutically inequivalent status.

Net sales for Specialty Generics by geography were as follows (dollars in millions):

	Three Months Ended		
	December 30, 2016	December 25, 2015	Percentage Change
U.S.	$ 178.5	$ 215.3	(17.1)%
Europe, Middle East and Africa	22.7	22.1	2.7
Other	11.7	20.2	(42.1)
Net sales	$ 212.9	$ 257.6	(17.4)

Net sales for Specialty Generics by key products were as follows (dollars in millions):

	Three Months Ended		
	December 30, 2016	December 25, 2015	Percentage Change
Hydrocodone (API) and hydrocodone-containing tablets	$ 23.2	$ 36.7	(36.8)%
Oxycodone (API) and oxycodone-containing tablets	24.3	28.9	(15.9)
Methylphenidate ER	22.0	31.2	(29.5)
Other controlled substances	104.9	109.7	(4.4)
Other products	38.5	51.1	(24.7)
Specialty Generics	$ 212.9	$ 257.6	(17.4)

Operating Income

Operating income by segment and as a percentage of segment net sales for the three months ended December 30, 2016 and December 25, 2015 is shown in the following table (dollars in millions):

	Three Months Ended			
	December 30, 2016		December 25, 2015	
Specialty Brands	$ 317.2	52.6%	$ 269.1	49.5%
Specialty Generics	52.7	24.8	115.2	44.7
Segment operating income	369.9	45.3	384.3	48.0
Unallocated amounts:				
Corporate and allocated expenses	(181.4)		(44.6)	
Intangible asset amortization	(175.7)		(173.4)	
Restructuring and related charges, net [1]	(5.3)		(4.2)	
Non-restructuring impairment	(214.3)		—	
Total operating (loss) income	$ (206.8)		$ 162.1	

(1) Includes restructuring-related accelerated depreciation.

Specialty Brands. Operating income for the three months ended December 30, 2016 increased $48.1 million to $317.2 million, compared with $269.1 million for the three months ended December 25, 2015. Operating margin increased to 52.6% for the three months ended December 30, 2016, compared with 49.5% for the three months ended December 25, 2015. The increase in operating income and margin was impacted by the $59.9 million increase in net sales, primarily attributable to Acthar volume growth and the fiscal 2016 Hemostasis product acquisition. The increase in gross profit also reflects a $12.6 million decrease in expense associated with fair value adjustments of acquired inventory. SG&A and R&D expenses were reasonably consistent across both periods.

Specialty Generics. Operating income for the three months ended December 30, 2016 decreased $62.5 million to $52.7 million, compared with $115.2 million for the three months ended December 25, 2015. Operating margin decreased to 24.8% for the three months ended December 30, 2016, compared with 44.7% for the three months ended December 25, 2015. The decrease in operating income and margin was impacted by the $44.7 million decrease in net sales due to customer consolidation and additional competitors that has led to price decreases, which resulted in a $53.2 million unfavorable gross profit impact. The gross profit impact exceeded the net sales impact primarily due to unfavorable product mix. In addition, there were increases in SG&A and R&D expenses of $9.3 million in total.

Corporate and allocated expenses. Corporate and allocated expenses were $181.4 million and $44.6 million for the three months ended December 30, 2016 and December 25, 2015, respectively. The three months ended December 30, 2016 included charges related to a $102.0 million settlement with the FTC and the Settling States and $45.0 million associated with the recognition of previously deferred pension related losses upon lump sum distribution to employees under our pension plan termination. Additional charges from deferred pension related losses are anticipated in the first half of calendar 2017 with the final settlement of outstanding obligations under these plans. The three months ended December 25, 2015, included $11.5 million of legal reserve accruals. The remaining $1.3 million increase is comprised of various minor increases and decreases.

Liquidity and Capital Resources

Significant factors driving our liquidity position include cash flows generated from operating activities, financing transactions, capital expenditures and cash paid in connection with acquisitions and license agreements. We believe that our future cash from operations, borrowing capacity under our revolving credit facility and access to capital markets will provide adequate resources to fund our working capital needs, capital expenditures and strategic investments for the foreseeable future.

A summary of our cash flows from operating, investing and financing activities is provided in the following table (dollars in millions):

	Three Months Ended	
	December 30, 2016	December 25, 2015
Net cash provided by (used in):		
Operating activities	$ 195.6	$ 311.4
Investing activities	(77.2)	215.6
Financing activities	(53.9)	(369.5)
Effect of currency exchange rate changes on cash and cash equivalents	(3.0)	(1.5)
Net increase in cash and cash equivalents	$ 61.5	$ 156.0

Operating Activities

Net cash provided by operating activities of $195.6 million for the three months ended December 30, 2016 was primarily attributable to income from continuing operations, as adjusted for non-cash items, in addition to a $125.3 million inflow from net investment in working capital. The working capital inflow was primarily driven by a $109.1 million increase in other assets and liabilities and a $36.5 million decrease in accounts receivable, net, partially offset by a $26.3 million increase in inventory. The increase in other assets and liabilities primarily resulted from the establishment of a reserve for the $102.0 million settlement with the FTC and the Settling States, the recognition of a $45.0 million charge associated with our pension settlement partially offset by payment of annual employee cash bonuses.

Net cash provided by operating activities of $311.4 million for the three months ended December 25, 2015 was primarily attributable to income from continuing operations, as adjusted for non-cash items, in addition to an $87.6 million inflow from net investment in working capital. The working capital inflow was primarily driven by an $82.3 million increase in the net tax related balances due to the timing of expected tax payments, and a $68.4 million decrease in accounts receivable, net, partially offset by a $35.6 million decrease in other assets and liabilities, a $14.5 million increase in inventories and a $13.0 million decrease in accounts payable. The decrease in accounts receivable, net was primarily due to timing of annual customer incentive payments and sales within the quarter. The $35.6 million decrease in other assets and liabilities resulted largely from the annual payout of employee cash bonuses for performance in the prior fiscal year and restructuring payments.

The aforementioned cash flows from operating activities include cash flows from the ongoing operations of the Nuclear Imaging and CMDS businesses that are included within discontinued operations. Subsequent to the completion of these transactions, we will no longer generate cash flows from these businesses. See further discussion of our discontinued operations in Note 3 of the Notes to Consolidated Financial Statements included within Item 1. Financial Statements of this Transition Report on Form 10-Q.

Investing Activities

Net cash used in investing activities was $77.2 million for the three months ended December 30, 2016, compared with a $215.6 million cash inflow for the three months ended December 25, 2015. The $292.8 million change primarily resulted from the receipt of $264.0 million in proceeds related to the sale of CMDS that occurred during the three months ended December 25, 2015. The remaining $28.8 million decrease in cash inflows was primarily impacted by a $16.2 million increase in capital expenditures and a $11.2 million increase in cash outflows for short-term investments.

Financing Activities

Net cash used in financing activities was $53.9 million for the three months ended December 30, 2016, compared with $369.5 million net cash used in financing activities for the three months ended December 25, 2015. The $315.6 million decrease in cash outflows largely resulted from a $128.0 million increase in cash proceeds from the issuance of debt, a $116.6 million decrease in share repurchases, and a $42.9 million decrease in repayment of debt. The remaining decrease in cash outflows was primarily impacted by a $30.0 million payment of contingent consideration to the former owners of BioVectra that was made during the three months ended December 25, 2015.

Debt and Capitalization

At December 30, 2016, the total principal amount of debt was $6,237.6 million as compared with the total principal amount of debt at September 30, 2016 of $6,135.6 million. The total principal amount of debt at December 30, 2016 was comprised of $3,938.3 million of fixed-rate instruments, $1,948.5 million of variable-rate term loans, $250.0 million of borrowings under a variable-rate securitization program, $100.0 million of borrowings under a variable-rate revolving credit facility and $0.8 million of capital lease obligations. The variable-rate term loan interest rates are based on LIBOR, subject to a minimum LIBOR level of 0.75% with interest payments generally expected to be payable every 90 days, and requires quarterly principal payments equal to 0.25% of the original principal amount. As of December 30, 2016, our fixed-rate instruments have a weighted-average interest rate of 5.29% and pay interest at various dates throughout the fiscal year. Our receivable securitization program bears interest based on one-month LIBOR plus a margin of 0.80% and has a capacity of $250.0 million that may, subject to certain conditions, be increased to $300.0 million.

In November 2015, our Board of Directors authorized us to reduce our outstanding debt at our discretion. As market conditions warrant, we may from time to time repurchase debt securities issued by us, in the open market, in privately negotiated transactions, by tender offer or otherwise. Such repurchases, if any, will depend on prevailing market conditions, our liquidity requirements and other factors. The amounts involved may be material. During the three months ended December 30, 2016, we repurchased $7.0 million of face value of our debt.

At December 30, 2016, $271.8 million of our debt principal was classified as current, as these payments are expected to be made within the next twelve months.

In addition to the borrowing capacity under our receivable securitization program, we have a $500.0 million revolving credit facility. At December 30, 2016, we had $100.0 million outstanding under our revolving credit facility. As such, there was $400.0 million of additional borrowing capacity under our revolving credit facility.

As of December 30, 2016, we were, and expect to remain, in full compliance with the provisions and covenants associated with our debt agreements.

Commitments and Contingencies

Legal Proceedings

We are subject to various legal proceedings and claims, including patent infringement claims, product liability matters, environmental matters, employment disputes, contractual disputes and other commercial disputes, including those described in Note 16 of notes to the unaudited condensed consolidated financial statements. We believe that these legal proceedings and claims likely will be resolved over an extended period of time. Although it is not feasible to predict the outcome of these matters, we believe, unless indicated in Note 16 of notes to the unaudited condensed consolidated financial statements, given the information currently available, that their ultimate resolutions will not have a material adverse effect on our financial condition, results of operations and cash flows.

Guarantees

In disposing of assets or businesses, we have historically provided representations, warranties and indemnities to cover various risks and liabilities, including unknown damage to the assets, environmental risks involved in the sale of real estate, liability to investigate and remediate environmental contamination at waste disposal sites and manufacturing facilities, and unidentified tax liabilities related to periods prior to disposition. We assess the probability of potential liabilities related to such representations, warranties and indemnities and adjust potential liabilities as a result of changes in facts and circumstances. We believe, given the information currently available, that their ultimate resolutions will not have a material adverse effect on our financial condition, results of operations and cash flows.

In connection with the sale of the Specialty Chemicals business (formerly known as Mallinckrodt Baker) in fiscal 2010, we agreed to indemnify the purchaser with respect to various matters, including certain environmental, health, safety, tax and other matters. The indemnification obligations relating to certain environmental, health and safety matters have a term of 17 years from the date of sale, while some of the other indemnification obligations have an indefinite term. The amount of the liability relating to all of these indemnification obligations included in other liabilities on our unaudited condensed consolidated balance sheet as of December 30, 2016 was $15.1 million, of which $12.4 million related to environmental, health and safety matters. The value of the environmental, health and safety indemnity was measured based on the probability-weighted present value of the costs expected to be incurred to address environmental, health and safety claims made under the indemnity. The aggregate fair value of these indemnification obligations did not differ significantly from their aggregate carrying value at December 30, 2016. As of December 30, 2016, the maximum future payments we could be required to make under these indemnification obligations was $71.0 million. We were required to pay $30.0 million into an escrow account as collateral to the purchaser, of which $19.0 million remained in other assets on our unaudited condensed consolidated balance sheet at December 30, 2016.

We have recorded liabilities for known indemnification obligations included as part of environmental liabilities, which are discussed in Note 16 of the unaudited notes to condensed consolidated financial statements.

In addition, we are also liable for product performance, and have established accruals as necessary; however, we believe, given the information currently available, that the ultimate resolution of these obligations will not have a material adverse effect on our financial condition, results of operations and cash flows.

Off-Balance Sheet Arrangements

We are required to provide the U.S. Nuclear Regulatory Commission financial assurance demonstrating our ability to fund the decommissioning of our Maryland Heights, Missouri radiopharmaceuticals production facility upon closure, though we do not intend to close this facility. We have provided this financial assurance in the form of surety bonds totaling $30.2 million. As of December 30, 2016, we had various other letters of credit, guarantees and surety bonds totaling $28.4 million.

We exchanged title to $73.7 million of our plant assets in return for an equal amount of Industrial Revenue Bonds ("IRB") issued by Saint Louis County. We also simultaneously leased such assets back from Saint Louis County under a capital lease expiring December 2025, the terms of which provide us with the right of offset against the IRBs. The lease also provides an option for us to repurchase the assets at the end of the lease for nominal consideration. These transactions collectively result in a property tax abatement for ten years from the date the property was placed in service. Due to the right of offset, the capital lease obligations and IRB assets are recorded net, and therefore do not appear in the unaudited condensed consolidated balance sheets. We expect that the right of offset will be applied to payments required under these arrangements.

In addition, the separation and distribution agreement entered into with Covidien provides for cross-indemnities principally designed to place financial responsibility of the obligations and liabilities of our business with us and financial responsibility for the obligations and liabilities of Covidien's remaining business with Covidien, among other indemnities.

Critical Accounting Policies and Estimates

The preparation of our unaudited condensed consolidated financial statements in conformity with accounting principles generally accepted in the U.S. requires management to use judgment in making estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses and related disclosure of contingent assets and liabilities.

We believe that our accounting policies for revenue recognition, goodwill and other intangible assets, acquisitions, contingencies and income taxes are based on, among other things, judgments and assumptions made by management that include inherent risks and uncertainties. During the three months ended December 30, 2016, there were no significant changes to these policies or in the underlying accounting assumptions and estimates used in the above critical accounting policies from those disclosed in our Annual Report on Form 10-K for the year ended September 30, 2016.

Forward-Looking Statements

We have made forward-looking statements in this Transition Report on Form 10-Q that are based on management's beliefs and assumptions and on information currently available to management. Forward-looking statements include, but are not limited to, information concerning our possible or assumed future results of operations, business strategies, financing plans, competitive position, potential growth opportunities, potential operating performance improvements, the effects of competition and the effects of future legislation or regulations. Forward-looking statements include all statements that are not historical facts and can be identified by the use of forward-looking terminology such as the words "believe," "expect," "plan," "intend," "project," "anticipate," "estimate," "predict," "potential," "continue," "may," "should" or the negative of these terms or similar expressions.

Forward-looking statements involve risks, uncertainties and assumptions. Actual results may differ materially from those expressed in these forward-looking statements. You should not place undue reliance on any forward-looking statements.

The risk factors included within Item 1A. of our Annual Report on Form 10-K for the fiscal year ended September 30, 2016 and within Part II, Item 1A of this Transition Report on Form 10-Q could cause our results to differ materially from those expressed in forward-looking statements. There may be other risks and uncertainties that we are unable to predict at this time or that we currently do not expect to have a material adverse effect on our business.

These forward-looking statements are made as of the filing date of this Transition Report on Form 10-Q. We expressly disclaim any obligation to update these forward-looking statements other than as required by law.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Our operations include activities in the U.S. and countries outside of the U.S. These operations expose us to a variety of market risks, including the effects of changes in interest rates and currency exchange rates. We monitor and manage these financial exposures as an integral part of our overall risk management program. We do not utilize derivative instruments for trading or speculative purposes.

Interest Rate Risk

Our exposure to interest rate risk relates primarily to our variable-rate debt instruments, which bear interest based on LIBOR plus margin. As of December 30, 2016, our outstanding debt included $1,948.5 million variable-rate debt on our senior secured term loans, $100.0 million on our senior unsecured revolving credit facility and $250.0 million variable-rate debt on our receivables securitization program. Assuming a one percent increase in the applicable interest rates, in excess of applicable minimum floors, quarterly interest expense would increase by approximately $5.7 million.

The remaining outstanding debt as of December 30, 2016 is fixed-rate debt. Changes in market interest rates generally affect the fair value of fixed-rate debt, but do not impact earnings or cash flows.

Currency Risk

Certain net sales and costs of our non-U.S. operations are denominated in the local currency of the respective countries. As such, profits from these subsidiaries may be impacted by fluctuations in the value of these local currencies relative to the U.S. Dollar. We also have significant intercompany financing arrangements that may result in gains and losses in our results of operations. In an effort to mitigate the impact of currency exchange rate effects we may hedge certain operational and intercompany transactions; however, our hedging strategies may not fully offset gains and losses recognized in our results of operations.

The unaudited condensed consolidated statement of income is significantly exposed to currency risk from intercompany financing arrangements, which primarily consist of intercompany debt and intercompany cash pooling, where the denominated currency of the transaction differs from the functional currency of one or more of our subsidiaries. We performed a sensitivity analysis for these arrangements as of December 30, 2016 that measures the potential unfavorable impact to income from continuing operations before income taxes from a hypothetical 10.0% adverse movement in foreign exchange rates relative to the U.S. Dollar, with all other variables held constant. The aggregate potential unfavorable impact from a hypothetical 10.0% adverse change in foreign exchange rates was $18.3 million as of December 30, 2016. This hypothetical loss does not reflect any hypothetical benefits that would be derived from hedging activities, including cash holdings in similar foreign currencies that we have historically utilized to mitigate our exposure to movements in foreign exchange rates.

The financial results of our non-U.S. operations are translated into U.S. Dollars, further exposing us to currency exchange rate fluctuations. We have performed a sensitivity analysis as of December 30, 2016 that measures the change in the net financial position arising from a hypothetical 10.0% adverse movement in the exchange rates of the Euro and the Canadian Dollar, our most widely used foreign currencies, relative to the U.S. Dollar, with all other variables held constant. The aggregate potential change in net financial position from a hypothetical 10.0% adverse change in the above currencies was $14.3 million as of December 30, 2016. The change in the net financial position associated with the translation of these currencies is generally recorded as an unrealized gain or loss on foreign currency translation within accumulated other comprehensive income in shareholders' equity of our unaudited condensed consolidated balance sheets.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures designed to ensure that information required to be disclosed in reports filed under the Securities Exchange Act of 1934, as amended ("the Exchange Act"), is recorded, processed, summarized and reported within the specified time periods, and that such information is accumulated and communicated to management, including our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), as appropriate, to allow timely decisions regarding required disclosure.

Our management, with the participation of our CEO and CFO, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Transition Report on Form 10-Q. Based on that evaluation, our CEO and CFO concluded that, as of that date, our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 30, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

We are subject to various legal proceedings and claims, including patent infringement claims, product liability matters, environmental matters, employment disputes, contractual disputes and other commercial disputes, including those described in Note 16 of the unaudited notes to condensed consolidated financial statements. We believe that these legal proceedings and claims likely will be resolved over an extended period of time. Although it is not feasible to predict the outcome of these matters, we believe, unless indicated in Note 16 of the unaudited notes to condensed consolidated financial statements, given the information currently available, that their ultimate resolutions will not have a material adverse effect on our financial condition, results of operations and cash flows. For further information on pending legal proceedings, refer to Note 16 of notes to condensed consolidated financial statements.

Item 1A. Risk Factors.

There have been no material changes to the risk factors previously disclosed in Part I, Item 1A. “Risk Factors” in our Annual Report on Form 10-K for the year ended September 30, 2016, filed with the SEC on November 29, 2016.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

(c) Issuer Purchases of Securities

The following table summarizes the repurchase activity of our ordinary shares during the three months ended December 30, 2016. The repurchase activity presented below includes both market repurchases of shares and deemed repurchases in connection with the vesting of restricted share units under employee benefit plans to satisfy minimum statutory tax withholding obligations.

On November 19, 2015, our Board of Directors authorized a $500.0 million share repurchase program (the “November 2015 Program”), which was completed in the three months ended December 30, 2016. The November 2015 Program commenced after the $300.0 million share repurchase program authorized by our Board of Directors on January 23, 2015 (the “January 2015 Program”) was completed in the three month period ended December 25, 2015. On March 16, 2016, our Board of Directors authorized an additional $350.0 million share repurchase program (the “March 2016 Program”) which commenced upon the completion of the November 2015 Program. The March 2016 Program has no time limit or expiration date, and the Company currently expects to fully utilize the program.

	Total Number of Shares Purchased	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares That May Yet Be Purchased Under Plans or Programs
October 1, 2016 to October 28, 2016	1,321,053	$ 69.77	1,344,167	$ 330.7
October 29, 2016 to December 2, 2016	211	65.89	—	330.7
December 3, 2016 to December 30, 2016	1,224,531	52.73	1,220,846	266.0

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Exhibit
2.1	First Amendment to Share Purchase Agreement, dated as of December 15, 2016, by and among Mallinckrodt Chemical Holdings (U.K.) Limited, Mallinckrodt Netherlands Holdings B.V., GLO Dutch Bidco B.V. and GLO US Bidco, LLC. (incorporated by reference to Exhibit 2.2 to the Company's Current Report on Form 8-K filed January 27, 2017).
3.1	Certificate of Incorporation of Mallinckrodt plc (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed July 1, 2013).
3.2	Amended and Restated Memorandum and Articles of Association of Mallinckrodt plc (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed July 1, 2013).
10.1	Second Amendment to the Note Purchase Agreement, dated as of September 4, 2015, among Mallinckrodt Securitization S.A.R.L., the persons from time to time party thereto as purchasers, PNC Bank, National Association, as administrative agent, and Mallinckrodt LLC, as servicer.
10.2	Third Amendment to the Note Purchase Agreement, dated as of November 18, 2016, among Mallinckrodt Securitization S.A.R.L., the persons from time to time party thereto as purchasers, PNC Bank, National Association, as administrative agent, and Mallinckrodt LLC, as servicer.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certifications of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Interactive Data File (Form 10-Q for the transition period ended December 30, 2016 filed in XBRL). The financial information contained in the XBRL-related documents is "unaudited" and "unreviewed."

The agreements and other documents filed as exhibits to this report are not intended to provide factual information or other disclosure other than with respect to the terms of the agreements or other documents themselves, and you should not rely on them for that purpose. In particular, any representations and warranties made by us in these agreements or other documents were made solely within the specific context of the relevant agreement or document and may not describe the actual state of affairs as of the date they were made or at any other time.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

MALLINCKRODT PUBLIC LIMITED COMPANY

By: /s/ Matthew K. Harbaugh

Matthew K. Harbaugh
Executive Vice President and Chief Financial Officer
(principal financial officer)

Date: February 7, 2017

EXHIBIT 17

Mallinckrodt Plans Spin-Off of Specialty Generics Business to Shareholders

-- Transaction expected to create two differentiated pharmaceutical companies with scale - One focused on innovative specialty pharmaceutical brands; One with a portfolio of niche specialty generic products, active pharmaceutical ingredients (APIs), and non-promoted brands including the AMITIZA® product --

-- Transaction expected to be completed in the second half of 2019 --

-- Spun-off company will assume the Mallinckrodt name; Specialty Pharmaceutical Brands company will be renamed --

Mallinckrodt Pharmaceuticals

NEWS PROVIDED BY
Mallinckrodt plc →
Dec 06, 2018, 06:00 ET

STAINES-UPON-THAMES, United Kingdom, Dec. 6, 2018 /PRNewswire/ -- Mallinckrodt plc (NYSE: MNK), a leading global specialty pharmaceutical company, today announced plans to spin off a new company consisting of Mallinckrodt's Specialty Generics/Active Pharmaceutical Ingredients (Specialty Generics) business and AMITIZA® (lubiprostone) to Mallinckrodt shareholders, subject to final Board approval. The separation is expected to create two independent, appropriately capitalized, publicly traded companies – one focused on innovative specialty pharmaceutical brands, the other concentrated primarily in niche specialty generic products and API manufacturing – each positioned to optimize future success as they pursue independent growth strategies.

The planned separation is expected to be executed through a pro-rata distribution of common stock to Mallinckrodt's shareholders that is generally tax-free for U.S. federal income tax purposes. The spin-off is projected to be completed in the second half of 2019 or sooner. It is anticipated that the spun-off company will be listed on the New York Stock Exchange (NYSE) and will assume the Mallinckrodt name and ticker symbol (MNK).

The 'remaining' independent Specialty Pharmaceutical Brands company, whose goal is to improve outcomes for underserved patients with severe and critical conditions, will continue to focus on its portfolio of innovative marketed and development products. **Mark Trudeau,** current **President and Chief Executive Officer**, will lead the business. The remaining company will be renamed at a later date.

Angus Russell, Mallinckrodt's Chairman of the Board, said, "Over the past five years, Mallinckrodt has transformed its business through a series of strategic transactions – acquiring a portfolio of marketed and development stage pharmaceutical brands that can drive growth, and divesting non-core assets that could be better maximized by others. In 2016 the Board began to explore a range of strategic alternatives for the company's Specialty Generics business, and believes there is a strong rationale and opportunity to create two new, appropriately capitalized, independent companies that have the potential to unlock and increase value over the long term. We expect this separation will result in greater strategic focus, allowing each business to more effectively enhance returns by commercializing new and current product offerings; drive innovation by allocating resources to the areas of highest opportunity; and pursue growth and investment strategies more directly aligned with each company's respective goals."

Mark Trudeau said, "Today's announcement is another important step forward in our journey to become an innovation-driven, pure-play, specialty pharmaceutical brands growth company. We believe this separation will further enhance our strategic focus and strengthen our balance sheet. It should also provide us with additional liquidity to support investments in our in-line brands and development portfolio and strategically allocate capital."

Trudeau added, "The spin-off of the Specialty Generics business creates an exciting new company which we believe will be well positioned to grow. Operating independently will allow this new company to more rapidly capitalize on its growth opportunities to enhance value."

PROFILE OF THE NEW SPECIALTY GENERICS COMPANY

For the twelve months ended September 28, 2018, the collective net sales from the new Specialty Generics company exceeded $850 million on an as reported basis inclusive of the AMITIZA product since February 14, 2018.

With approximately 1,600 employees, the newly spun company will include a leading acetaminophen business, a portfolio of both API and generic finished dose forms of controlled substances and other drugs, a niche specialty generics development portfolio, and a strong U.S. manufacturing footprint. The inclusion of the AMITIZA product in the non-promoted assets to be spun off brings added manufacturing facilities and employees in Japan, and diversifies revenues further. Marketed in the U.S. and Japan by alliance partners, Mallinckrodt recognizes net sales from commercial partnership arrangements in the form of AMITIZA product sales, royalties and milestones. The new Specialty Generics company will be positioned financially to grow its ANDA[1] pipeline and expects to launch as many as five new products in 2019. The company will be headquartered in the St. Louis, Missouri area.

Matthew Harbaugh, currently Mallinckrodt's Executive Vice President and Chief Financial Officer (CFO) and President of the Specialty Generics business, is expected to become President and Chief Executive Officer of the new company upon completion of the spin off.

Harbaugh will step down as Mallinckrodt's CFO, effective immediately, to focus exclusively on preparing for separation, but will continue to serve as President of the Specialty Generics business and report to Trudeau. A search for Harbaugh's successor is underway. During this process, **George Kegler**, Mallinckrodt's Vice President of Finance, will serve as interim CFO. Announcements of the Board of Directors for the Specialty Generics business are expected at a later date.

Harbaugh said, "Mallinckrodt has a more than 150-year legacy of operations in St. Louis and a proud history of supplying the highest quality products to customers. As an independent, U.S.-based company, I am confident that we will be well positioned to advance our R&D[2] capabilities and continue to maintain our category leadership in controlled substances."

"Matt has been involved in the Specialty Generics business for over a decade," said Trudeau. "We're very pleased to have someone with his leadership experience take the helm."

PROFILE OF THE SPECIALTY PHARMACEUTICAL BRANDS COMPANY

With net sales in excess of $2.3 billion[3] (inclusive of a $1 billion hospital portfolio and a robust innovative pipeline), the Specialty Pharmaceutical Brands company is expected to gain additional liquidity and financial flexibility from the transaction to enable continued strategic transformation and growth.

As reported on Nov. 6, Mallinckrodt's third quarter 2018 results showed strong customer demand for its branded hospital products – including **INOmax®** (nitric oxide) gas, for inhalation, **OFIRMEV®** (acetaminophen) injection and the **Therakos®** immunotherapy platform – and improved performance for **H.P. Acthar® Gel** (repository corticotropin injection). Solid execution combined with tight expense control helped support increased R&D investments in the company's innovative pipeline. Operational excellence and continued strong commercial execution throughout 2018 have also been the catalysts for Mallinckrodt to raise its guidance for adjusted diluted earnings per share in each of the last two quarters.

The company expects to achieve a number of key milestones for its pharmaceutical brands in coming quarters. It anticipates top-line results from both the completed rheumatoid arthritis clinical trial and multiple sclerosis registry for H.P. Acthar Gel as early as the first half of 2019. Additionally, in the second half of 2019, the company is targeting completion of enrollment in Phase 4 trials in uveitis and lupus for the drug, and anticipates completing enrollment in the H.P. Acthar Gel Phase 2 trial in amyotrophic lateral sclerosis as well. Top-line results from the company's development program for **CPP-1X/sulindac** are anticipated in the first quarter of 2019, and the pivotal trial results for both **StrataGraft®** viable engineered skin tissue and **terlipressin** are expected to be available in the second half of the year.

Following the spin-off, ordinary shares of the renamed Specialty Pharmaceutical Brands company will continue to trade on the NYSE. The company will maintain its global headquarters in Staines-upon-Thames, United Kingdom, and its principal U.S. office in Bedminster, N.J. The company also plans to maintain other facilities throughout the United States and in Australia, Canada, Ireland, Japan, Luxembourg and Switzerland.

NEXT STEPS IN THE SEPARATION PROCESS

With the pursuit of strategic alternatives for the Specialty Generics business actively underway for more than two years, important progress has already been made in key areas that the company believes will simplify and support a relatively short separation process. Completion of

the separation transaction will be subject to certain conditions, including final Board approval, an opinion from tax counsel regarding the treatment of the spin-off as generally tax-free for U.S. federal income tax purposes to Mallinckrodt shareholders, and the U.S. Securities and Exchange Commission (SEC) declaring the Form 10 registration statement effective. There can be no assurance regarding the final allocation of assets between the two companies, the ultimate timing of the proposed separation, or that the spin-off will be completed.

CONFERENCE CALL AND WEBCAST

Mallinckrodt will hold a conference call on Thursday, Dec. 6, 2018, beginning at 8:00 a.m. U.S. Eastern Time. This call can be accessed in three ways:

- At the Mallinckrodt website: http://www.mallinckrodt.com/investors.
- By telephone: For both listen-only participants and those who wish to take part in the question-and-answer portion of the call, the telephone dial-in number in the U.S. is (877) 359-9508. For participants outside the U.S., the dial-in number is (224) 357-2393. Callers will need to provide the Conference ID of 5349569.
- Through an audio replay: A replay of the call will be available beginning at 11:00 a.m. Eastern Time on Thursday, Dec. 6, 2018, and ending at 11:59 p.m. Eastern Time on Thursday, Dec. 20, 2018. Dial-in numbers for U.S.-based participants are (855) 859-2056 or (800) 585-8367. Participants outside the U.S. should use the replay dial-in number of (404) 537-3406. All callers will be required to provide the Conference ID of 5349569.

ADVISORS

Goldman, Sachs & Co. is acting as financial advisor on the spin-off and Wachtell, Lipton, Rosen & Katz is acting as legal advisor.

ABOUT THE SPECIALTY GENERICS DISPOSAL GROUP

In light of this announcement, and in accordance with the accounting literature pertaining to discontinued operations, it is expected that the Specialty Generics Disposal Group, which is currently reflected in discontinued operations, will be brought back into Mallinckrodt's continuing operations in conjunction with its next quarterly earnings announcement and within its 2018 Form 10-K to be filed in February 2019.

ABOUT AMITIZA

AMITIZA (lubiprostone), a leading global product in the branded constipation market, is approved by the U.S. Food and Drug Administration for treatment of chronic idiopathic constipation in adults, irritable bowel syndrome with constipation in women 18 years of age and older, and opioid-induced constipation in adult patients with chronic, non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent opioid dosage escalation. The AMITIZA product is a chloride channel activator which increases fluid secretion and motility of the intestine, facilitating passage of stool.

ABOUT MALLINCKRODT

Mallinckrodt is a global business that develops, manufactures, markets and distributes specialty pharmaceutical products and therapies. Areas of focus include autoimmune and rare diseases in specialty areas like neurology, rheumatology, nephrology, pulmonology and ophthalmology; immunotherapy and neonatal respiratory critical care therapies; analgesics and gastrointestinal products. To learn more about Mallinckrodt, visit www.mallinckrodt.com.

Mallinckrodt uses its website as a channel of distribution of important company information, such as press releases, investor presentations and other financial information. It also uses its website to expedite public access to time-critical information regarding the company in advance of or in lieu of distributing a press release or a filing with the SEC disclosing the same information. Therefore, investors should look to the Investor Relations page of the website for important and time-critical information. Visitors to the website can also register to receive automatic e-mail and other notifications alerting them when new information is made available on the Investor Relations page of the website.

CAUTIONARY STATEMENTS RELATED TO FORWARD-LOOKING STATEMENTS

Statements in this document that are not strictly historical, including statements regarding future financial condition and operating results, economic, business, competitive and/or regulatory factors affecting Mallinckrodt's businesses and any other statements regarding events or developments the company believes or anticipates will or may occur in the future, may be "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995, and involve a number of risks and uncertainties.

There are a number of important factors that could cause actual events to differ materially from those suggested or indicated by such forward-looking statements and you should not place undue reliance on any such forward-looking statements. These factors include risks and uncertainties related to, among other things: the proposed spin-off of the Specialty Generics business inclusive of Mallinckrodt's AMITIZA product, including the costs associated with the contemplated separation and spin-off, the expected benefits of the transaction, and the expected timeframe to complete such a transaction; general economic conditions and conditions affecting the industries in which Mallinckrodt operates; the commercial success of Mallinckrodt's products; Mallinckrodt's ability to realize anticipated growth, synergies and cost savings from acquisitions; conditions that could necessitate an evaluation of Mallinckrodt's goodwill and/or intangible assets for possible impairment; changes in laws and regulations; Mallinckrodt's ability to successfully integrate acquisitions of operations, technology, products and businesses generally and to realize anticipated growth, synergies and cost savings; Mallinckrodt's and Mallinckrodt's licensers' ability to successfully develop or commercialize new products; Mallinckrodt's and Mallinckrodt's licensers' ability to protect intellectual property rights; Mallinckrodt's ability to receive procurement and production quotas granted by the U.S. Drug Enforcement Administration; customer concentration; Mallinckrodt's reliance on certain individual products that are material to its financial performance; cost containment efforts of customers, purchasing groups, third-party payers and governmental organizations; the reimbursement practices of a small number of public or private insurers; pricing pressure on certain of Mallinckrodt's products due to legal changes or changes in insurers' reimbursement practices resulting from recent increased public scrutiny of healthcare and pharmaceutical costs; limited clinical trial data for H.P. Acthar Gel; complex reporting and payment obligations under healthcare rebate programs; Mallinckrodt's ability to navigate price fluctuations; future changes to U.S. and foreign tax laws; Mallinckrodt's ability to achieve expected benefits from restructuring activities; complex manufacturing processes; competition; product liability losses and other litigation liability; ongoing governmental investigations; material health, safety and environmental liabilities; retention of key personnel; conducting business internationally; the effectiveness of information technology infrastructure; and cybersecurity and data leakage risks.

These and other factors are identified and described in more detail in the "Risk Factors" section of Mallinckrodt's Annual Report on Form 10-K for the fiscal year ended December 29, 2017. The forward-looking statements made herein speak only as of the date hereof and Mallinckrodt

does not assume any obligation to update or revise any forward-looking statement, whether as a result of new information, future events and developments or otherwise, except as required by law.

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[1] Abbreviated New Drug Application

[2] Research and Development

[3] Reflects last twelve months ended September 28, 2018 on an as reported basis

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